APPENDIX

APPENDIX A

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

Nos. 81-2190, 81-2191 and 81-2469

MOBAY CHEMICAL CORPORATION,
Appellant in 81-2190 and 81-2191

v.

ANNE M. GORSUCH, Administrator
ENVIRONMENTAL PROTECTION AGENCY,
Appellee

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA
(D.C. Civil Nos. 79-0591 and 81-0373)

PENNWALT CORPORATION,
Appellant in 81-2469

v.

ANNE M. GORSUCH, Administrator
ENVIRONMENTAL PROTECTION AGENCY,
Appellee

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA
(D.C. Civil No. 80-2400)

Argued April 28, 1982
Before: ALDISERT, WEIS and BECKER, *Circuit Judges*
(Opinion filed June 22, 1982)

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OPINION OF THE COURT

WEIS, *Circuit Judge.*

In this appeal, two pesticide manufacturers contend that the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) permits an uncompensated taking of their proprietary data. In addition, one manufacturer asserts that certain regulations promulgated by the Environmental Protection Agency are inconsistent with the statute and were adopted without proper observance of the Administrative Procedure Act. We reject the constitutional challenges but, finding lack of compliance with the APA, grant the EPA six months to adopt regulations in the appropriate manner.

Three cases have been consolidated here. In the suit brought in the Eastern District of Pennsylvania, Pennwalt Corporation challenged the constitutionality of the 1978 amendments to FIFRA, 7 U.S.C. §136 *et seq.*, but the district court granted summary judgment in favor of the EPA. Mobay Chemical Corporation mounted a similar attack in the Western District of Pennsylvania, and questioned certain implementing regulations promulgated in 1979 by the EPA. After trial, the district court upheld the statute and regulations. *Mobay Chemical Corp. v. Costle*, 517 F.Supp. 254 (W.D. Pa. 1981). In a separate action, the court modified an injunction against the EPA entered in *Mobay Chemical Corp. v. Costle*, 447 F.Supp. 811 (W.D. Mo. 1978), before the 1978 amendments were enacted and before the case had been transferred to Pennsylvania. Because the 1978 legislation authorized what the Missouri court had enjoined, the injunction was modified to reflect the statutory changes. *Mobay Chemical Corporation v. Costle*, 517 F.Supp. 252 (W.D. Pa. 1981).

I

FIFRA was enacted originally in 1947. Ch. 125, 61 Stat. 163 (1947). It makes the EPA responsible for regulating pesticides by "registering" only those products whose use will not harm the environment. 7 U.S.C. §136a. As part of the licensing process, applicants must submit test data to the EPA demonstrating the safety and efficacy of their products. The development of new pesticides requires a great deal of time, money and skill, and consequently the test data represent a substantial investment by applicants.

As amended by the Federal Environmental Pesticide Control Act of 1972, FIFRA permitted applicants to designate portions of their data as trade secrets and prohibited the EPA from disclosing this information. Section 10(a) & (b), Pub. L. No. 92-516, 86 Stat. 973 (1972). In addition, the statute was changed so that data submitted in support of an application could not be considered by the agency in support of a subsequent application, unless two conditions were met. First, the later applicant had to compensate the original submitter for use of the data, and second, the original submitter did not designate the data as trade secrets. §3(c)(1)(D). The 1975 amendments to this section further limited the protection against use of information to data submitted on or after January 1, 1970. Act of Nov. 28, 1975, Pub. L. No. 94-140, 89 Stat. 755 (1975).

The Federal Pesticide Act of 1978 removed the trade secret protection over test data provided by §10(b) of the earlier legislation. Pub. L. No. 95-396, 92 Stat. 819 (1978). Applicants were granted a 10-year period of exclusive use for information about new chemicals contained in pesticides registered after September 30, 1978. Section 3(c)(1)(D)(i), 7 U.S.C. §136a(c)(1)(D)(i). But

the EPA may, without the permission of the original applicant, use data presented after December 31, 1969, which is not entitled to exclusive use, in support of another application for 15 years following the original submission. In this event, the later applicant must offer to compensate the original submitter. Section 3(c)(1)(D)(ii), 7 U.S.C. §136a(c)(1)(D)(ii). If the parties cannot agree on the amount of compensation, either may initiate binding arbitration proceedings. *Id.* No limitation exists on the EPA's use of data that does not qualify for either the 10-year period of exclusive use or the 15-year period of compensation. Section 3(c)(1)(D)(iii), 7 U.S.C. §136a(c)(1)(D)(iii).

The 1978 amendments also provide for broader disclosure of test data. The EPA may make available to the public any information about the safety and efficacy of pesticides. Section 10(d), 7 U.S.C. §136h(d). *See also*, §3(c)(2)(A), 7 U.S.C. §136a(c)(2)(A). If necessary, the agency also may disclose trade secret data to contractors with the United States, so long as adequate security measures are taken. Section 10(e), 7 U.S.C. §136h(e). The EPA may not, however, disclose data to foreign or multinational pesticide producers, unless the original submitter consents. Section 10(g), 7 U.S.C. §136h(g).

Both Pennwalt and Mobay contend that the test data are trade secrets and, as such, constitute intellectual property of "incalculable value." In their view, the FIFRA provisions allowing the EPA to use and disclose the information amount to a taking without just compensation. The companies also argue that the provision for binding arbitration denies them the right to a judicial determination of just compensation.

We have reviewed the statutory amendments only briefly because the challenges made to the constitutionality of the use provisions mirror the contentions advanced in *Chevron Chemical Co. v. Costle*, 641 F.2d 104 (3d Cir.), *cert. denied*, 452 U.S. 961 (1981). There, we reviewed at length the legislative history of the amendments and their predecessors, and analyzed the claims of property deprivation. We rejected the constitutional challenges, concluding that, in the "use" context, applicants do not have a property interest in data submitted to the EPA beyond that conferred by FIFRA itself.

As a panel, we are bound by *Chevron*. United States Court of Appeals for the Third Circuit Internal Operating Procedures Ch. VIIIC (1980). Morever, the arguments advanced in this appeal fail to convince us that *Chevron* should be reconsidered by the court *en banc*. We therefore reiterate that an applicant does not have a property interest in data submitted to the EPA that would prevent the agency from using the information in considering other requests for registration. Since there is no protected property interest as against use of the data, we also reject the contention, as we did in *Chevron*, that the compulsory arbitration provision deprives the original submitters of the right to a judicial determination of just compensation. For the same reason, we will also uphold the action of the court for the Western District of Pennsylvania modifying the injunction against the EPA to reflect the changes made to FIFRA's use provisions by the 1978 amendments.[1]

Pennwalt and Mobay attempt to place FIFRA's disclosure provision beyond the *Chevron* holding. Although that case did not decide whether the EPA's disclosure of

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1. Mobay agrees that its two appeals from the Western District of Pennsylvania stand or fall together on the use issue.

data constitutes a taking, the same rationale applies to this issue with equal force. As we said in *Chevron*, an applicant has no "continuing property interest, beyond that provided by federal law, applicable to material furnished to a federal agency as a precondition to selling a product in interstate commerce." 641 F.2d at 116.

An applicant may retain his property rights in data by not disclosing it to anyone. But no taking occurs if the applicant chooses to present the information to the government in exchange for a registration with substantial commercial value. In another case, we rejected a similar constitutional claim where an agency's disclosure of a company's proprietary information was challenged as an uncompensated taking, saying: "[a] voluntary submission of information by an applicant seeking the economic advantages of a license can hardly be called a taking." *Westinghouse Electric Corp. v. United States*, 555 F.2d 82, 95 (3d Cir. 1977).

FIFRA's disclosure provision is not a blanket authorization for the EPA to release confidential information. It limits public disclosure of test data to such matters as the effects of pesticides on human, animal and plant life. Information disclosing manufacturing or quality control processes, details of methods for testing inert ingredients deliberately added to pesticides, and the identity or quantity of such inert ingredients, may not be made public unless necessary for safety purposes. In this circumstance, a mandatory 30-day notification period allows the data submitter to institute an action in a district court to challenge the proposed disclosure.

The principle of limited disclosure that Congress applied in §10 is neither startling nor new. Pesticides serve a useful and important function, but they also may present significant hazards. The public has a very real interest

in their use and abuse and may justifiably assert a need to have sufficient information for protection. Congress balanced the understandable desire of the manufacturers to keep their experimental results confidential against the public interest in protecting the health of the community. Both positions were pressed vigorously before Congress, and it adopted a middle ground by providing for limited disclosure. This legislative action was well within constitutional boundaries and we sustain it here.

In *Corn Products Refining Co. v. Eddy*, 249 U.S. 427 (1919), the Supreme Court had no difficulty in rejecting a taking challenge to a statute requiring disclosure of the confidential formula of a food product. After observing that the purpose of the law was to prevent adulteration and misbranding that might mislead purchasers as to the wholesomeness of the product, the Court said:

> "[I]t is too plain for argument that a manufacturer or vendor has no constitutional right to sell goods without giving to the purchaser fair information of what it is that is being sold. The right of a manufacturer to maintain secrecy as to his compounds and processes must be held subject to the right of the State, in the exercise of its police power and in promotion of fair dealing, to require that the nature of the product be fairly set forth."

249 U.S. at 431-32. *See also National Fertilizer Association v. Bradley*, 301 U.S. 178 (1937). The same principle requires us to reject Pennwalt's and Mobay's attacks on FIFRA's disclosure provision as well.

Mobay's final constitutional challenge is that FIFRA §3(g), 7 U.S.C. §136a(g), which directs the EPA to reregister all pesticides "in the most expeditious manner practicable," deprives the company of its right to compen-

sation for data that other applicants relied on in obtaining twenty-three previous registrations. In *Mobay Chemical Corp. v. Costle*, 447 F.Supp. 811 (W.D. Mo. 1978), the Missouri district court decided that the EPA violated the data compensation requirements of the 1972 amendments by failing to require other companies to compensate Mobay for the use of its data. The court refused to declare the registrations invalid, however, because Mobay would be compensated upon re-registration. At the time the Missouri court decided the case, the statute provided that re-registration was to be completed by October 21, 1977. The 1978 amendments removed this deadline, and Mobay asserts that this change is an uncompensated taking.

The district court for Western Pennsylvania held that the delay caused by the 1978 amendment does not amount to a constitutional violation. We agree, and note that the Missouri court did not rely on a set date for the completion of re-registration. On the contrary, that court knew that the process was behind schedule, observing that the statutory deadline had already passed. 447 F. Supp. at 823 n.18.

II

In addition to the constitutional challenges to FIFRA made by both appellants, Mobay attacks certain regulations adopted by the EPA. This assault has two phases —lack of conformity to the enabling statute, and failure to observe the rulemaking requirements set out in the Administrative Procedure Act.

As part of its program to implement the 1978 amendments, the EPA adopted a policy of generally granting only "conditional registrations" under FIFRA §3(c)(7), 7 U.S.C. §136a(c)(7). 40 C.F.R. §162.7(d) and (e). The agency wanted to use a new approach, known as the

"generic standards system," in considering registration and re-registration. 44 Fed. Reg. 76311-12 (Dec. 26, 1979). Under this system, the EPA intends to develop standards for each group of pesticide products containing the same active ingredient. Completion of the generic standards process is expected to take at least 10 years. In the meantime, only conditional registrations will be granted.

Mobay contends that FIFRA compels the EPA to review its data after receipt of an application and, as expeditiously as possible, either unconditionally register the pesticide, or deny the registration. Section 3(c)(3), (5), and (6), 7 U.S.C. §136a(c)(3), (5), and (6). The district court held, however, that the EPA's conditional registration policy does not contravene the statute.

Most of Mobay's fire is directed at the agency's "cite all", or data compensation, regulations. These require that, even if he has presented his own data, an applicant must rely on all information in the EPA files which are pertinent to an evaluation of his product and must compensate each data submitter individually. 40 C.F.R. 162.9-4,-5.

Mobay contends that the "cite all" regulations violate FIFRA because the statute allows an applicant a choice of three alternate methods of support. Section 3(c)(1)(D), 7 U.S.C. §136a(c)(1)(D). He may (1) proffer his own test data, "or alternatively" (2) cite that appearing in the public literature, or (3) rely on information previously submitted to the EPA. Since Mobay believes that its own data is adequate to support its applications, it would not choose to cite that of, and pay compensation to, other manufacturers.

At one stage of the proceedings in the district court, the EPA conceded that it shared Mobay's interpretation

of the statute.[2] At other times in the district court, however, and on appeal, the agency has taken the position that the "cite all" regulations are consistent with FIFRA. On these occasions, the EPA views the phrase "if requested by the Administrator" that appears in the subsection as authorizing it to demand cumulative rather than alternative methods of support. The district judge agreed that the regulations are supported by this reading of the statute.

Mobay also complained that an EPA data compensation regulation misconstrues the "formulator's exemption" created by the Act. Section 3(c)(2)(D), 7 U.S.C. §136a (c)(2)(D). This provision applies to an applicant who seeks to register an end-use product that incorporates a previously registered pesticide purchased from another manufacturer. The end-use applicant is not required to submit or cite data for the incorporated pesticide, nor to offer to pay compensation for the use of previously submitted data.

The EPA regulation exempts an end-use formulator from paying any firm for data bearing on the incorporated pesticide. 40 C.F.R. §162.9-7. Mobay asserts that the exemption should apply only to the manufacturer from whom the formulator purchased the pesticide, since presumably it has included a proportionate share of the test-

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2. Mobay submitted a set of requests for admissions to the EPA which we reproduce here along with the answers:

"42. Section 3(c)(1)(D) of the Act provides three distinct methods by which an applicant may satisfy the Act's requirements for data to support his application.

Answer: Admit.

43. The option to support an application by any of the methods provided in Section 3(c)(1)(D) of the Act lies with the applicant.

Answer: Admit."

ing expense in the price. On the other hand, says Mobay, every other manufacturer who has registered the pesticide is entitled to compensation. The district court disagreed and held that the regulation was consistent with the statute.

We need not decide whether the conditional registration and "cite all" regulations are an unreasonable interpretation of FIFRA because we accept Mobay's contention that the regulations were promulgated in violation of the notice-and-comment and effective date requirements of the Administrative Procedure Act. 5 U.S.C. §553(b) and (d), and §706(2)(D).

Congress enacted the 1978 FIFRA amendments on September 30, 1978. The EPA published proposed data compensation rules on June 20, 1977, based on the provisions of the then-current statute and on the agency's then-current policies. 42 Fed. Reg. 31284. As the agency admits, however, the 1978 amendments "drastically altered" the compensation portions of the Act. 44 Fed. Reg. 27945 (May 11, 1979).

On July 25, 1978, the EPA published an Advance Notice of Interim Final and Proposed Rulemaking (ANPR) for the conditional registration program, and solicited comments. It included a suggestion that commenters might also wish to address compensation for the use of data. 43 Fed. Reg. 32154-55. On October 6, 1978, the EPA circulated working drafts of the conditional registration and data compensation regulations to over 2500 interested groups, agencies, and organizations. See 44 Fed. Reg. 27932-33. Then, on October 10, 1978, the agency published a notice of open public meetings to be held in Washington, D.C. during the next month to solicit comments on the conditional registration of pesticides as well as on data review and compensation. 43 Fed. Reg. 46555.

On May 11, 1979, the EPA promulgated the present conditional registration regulations as interim final rules, and the data compensation regulations as final rules. 44 Fed. Reg. 27932, 27945. Both sets of regulations were made effective immediately.

The EPA recognized that the data compensation regulations "differ significantly" from those proposed in June 1977. 44 Fed. Reg. 27950-51. Nevertheless, it invoked the "good cause" exception to the APA's notice-and-comment requirements on the grounds that reproposal would be "contrary to the public interest" because of the long delay it would cause in resuming the registration program. 5 U.S.C. §553(b)(B). The EPA justified its action by noting that a working draft was circulated in October and public meetings were held in November 1978, and said it would revise the regulations to the extent appropriate, as judged by its experience and by comments received. Finally, the agency found that these same reasons constituted "good cause" for making the regulations effective immediately, instead of observing the 30-day period between publication and effective date that is otherwise required. 5 U.S.C. §553(d)(3).

The EPA decided not to publish the conditional registration regulations in proposed form because the ANPR, the circulated working draft, and the public meetings had already provided "considerable opportunity for public comment." 44 Fed. Reg. 27933. Publication of a general notice of proposed rule making is not necessary when the "persons subject thereto . . . otherwise have actual notice. . . ." 5 U.S.C. §553(b). The agency again asserted a compelling public interest in resuming the registration program as quickly as possible as a reason for making the regulations effective immediately.

The district court found that the June 1977 publication of the proposed data compensation regulations was insufficient notice, since it occurred more than one year before the relevant portion of FIFRA was significantly changed. Moreover, circulation of the working draft in October 1978 was an inadequate substitute for the notice-and-comment procedure because many pesticide companies received their copies too late for review and submission of comments.

The court concluded, however, that the EPA had good cause not to re-propose the data compensation regulations because of the need to resume the registration process quickly. As for the conditional registration regulations, the court found that the July 25, 1978 ANPR provided the public with sufficient notice and opportunity to comment. Finally, the court held that the same reasons that justified noncompliance with the notice-and-comment procedure for the data compensation regulations also constituted good cause for making both sets of regulations effective immediately.

In considering whether there was good cause for the agency to adopt the data compensation regulations without prior notice-and-comment, we are guided by the principle that the exception is to be narrowly construed. *American Iron & Steel Institute v. EPA*, 568 F.2d 284, 292 (3d Cir. 1977). Adherence to this principle led us twice before to strike down final regulations published by this agency. *Sharon Steel Corp. v. EPA*, 597 F.2d 377 (3d Cir. 1979); *American Iron & Steel Institute v. EPA*, 568 F.2d at 291-92. In *Sharon Steel*, as here, the EPA asserted an urgent need for action as grounds for disregarding the notice-and-comment procedure. The court rejected this contention, even though it was based on a statutory deadline, and also held that a period for com-

ments after promulgation of a rule cannot substitute for the prior notice and comment required by the APA. 597 F.2d at 381. *Cf. Philadelphia Citizens In Action v. Schweiker*, 669 F.2d 877 (3d Cir. 1982) (agency's invocation of good cause exception upheld).

We still adhere to this view of the matter today, and hold that the agency did not establish good cause to excuse compliance with the APA. As we said in *Sharon Steel*, "[p]rovision of prior notice and comment allows effective participation in the rulemaking process while the decisionmaker is still receptive to information and argument." 597 F.2d at 381. Suggestions from informed sources are especially valuable when, as here, the agency must implement a complex and technical statute.

The record here demonstrates the wisdom of the notice-and-comment procedure. The EPA seems to find FIFRA's mandate confusing because, as mentioned earlier, at trial it admitted that the statute gives applicants a choice of methods for supporting applications, whereas the agency's "cite all" regulations foreclose these alternatives. Understandably, those subject to the regulations profess confusion as well. The EPA's difficult task would have been facilitated had it scrupulously observed the notice-and-comment procedure, since it "enables the agency promulgating the rule to educate itself before establishing rules and procedures which have a substantial impact on those regulated." *Texaco, Inc. v. FPC*, 412 F.2d 740, 744 (3d Cir. 1969). Procedural regularity would also help to inspire public confidence in the agency's workings.

In evaluating whether the July 25, 1978 ANPR gave sufficient actual notice for the EPA to dispense with the usual APA procedures, "the adequacy of the notice must be tested by determining whether it would fairly apprise interested persons of the 'subjects and issues' before the

Agency." *American Iron & Steel Institute v. EPA*, 568 F.2d at 293. Inspection of the ANPR shows that it falls short of this standard. It states that "[t]he regulations will address the registration of pesticide products on a conditional basis, that is, contingent upon the later submission of certain data normally required prior to registration," and adds that "[t]he regulations will specifically discuss . . . the procedures and conditions under which conditional registrations will be granted." 43 Fed. Reg. 32155. Plainly, these generalities are insufficient to alert interested parties to the full extent of the "conditional only" program actually envisioned by the EPA. Consequently, we do not agree with the district court's conclusion that good cause for waiver of the APA has been demonstrated.

We are persuaded that the EPA's failure to observe the proper notice-and-comment procedure is directly responsible for many of the problems caused by the regulations. We therefore reject the agency's contention that its violation of the APA is only "harmless error." Nevertheless, we are convinced that to strike down the regulations immediately would generate confusion in the administrative process and unduly delay effective implementation of FIFRA's registration provisions.

In reviewing administrative actions, a court of appeals may exercise equitable powers in the choice of a remedy, as long as the court confines itself to the terms of the statute and does not improperly intrude on the agency's powers. *Sharon Steel Corp. v. EPA*, 597 F.2d at 381. Although appellants are entitled to relief, we should not fashion a remedy so broad as to endanger the Congressional plan for the control of pesticides. *Id.* To accommodate the conflicting interests at stake here, we shall delay for a period of six months the issuance of a

mandate invalidating the regulations. During that time, the EPA shall take all necessary steps to promulgate appropriate regulations in accordance with the Administrative Procedure Act.

The judgment of the District Court for the Eastern District of Pennsylvania, our docket No. 81-2469, will be affirmed. The judgment of the Western District of Pennsylvania in No. 81-2190 will be affirmed insofar as it rejected the constitutional challenge of the appellants, but will be vacated as to the EPA regulations which the district court sustained. The judgment of the Western District of Pennsylvania in No. 81-2191 will also be affirmed.

A True Copy:

Teste:

Clerk of the United States Court of Appeals for the Third Circuit

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

Nos. 81-2190, 81-2191 and 81-2469

MOBAY CHEMICAL CORPORATION,
Appellant in 81-2190 and 81-2191

vs.

ANNE M. GORSUCH, Administrator
ENVIRONMENTAL PROTECTION AGENCY

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA
(D. C. CIVIL Nos. 79-0591 and 81-0373)

PENNWALT CORPORATION,
Appellant in 81-2469

vs.

ANNE M. GORSUCH, Administrator
ENVIRONMENTAL PROTECTION AGENCY

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA
(D. C. Civil No. 80-2400)

Present: ALDISERT, WEIS, and BECKER, *Circuit Judges*

JUDGMENT

These causes came on to be heard on the records from the United States District Courts for the Western and Eastern Districts of Pennsylvania and were argued by counsel on April 28, 1982.

On consideration whereof, it is now here ordered and adjudged by this Court that the judgment of the District Court for the Eastern District of Pennsylvania entered July 24, 1981, in C.A. No. 81-2469 (Civil No. 80-2400) be, and the same is hereby affirmed. It is further ordered and adjudged that the judgment of the said District Court for the Western District of Pennsylvania entered June 12, 1981, in C.A. No. 81-2190 (Civil No. 79-591) be, and the same is hereby affirmed insofar as it rejected the constitutional challenge of the appellants, but vacated as to the EPA regulations sustained by the said District Court. It is further ordered and adjudged that the judgment of the said District Court for the Western District of Pennsylvania entered June 12, 1981, in C.A. No. 81-2191 (Civil No. 81-373) be, and the same is hereby affirmed. Costs taxed against appellants.

ATTESTS:

/s/ Sally Mrvos
Clerk

June 22, 1982

APPENDIX B

IN THE
UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF
PENNSYLVANIA

Civil Action No. 79-591

MOBAY CHEMICAL CORPORATION,
Plaintiff,

vs.

DOUGLAS M. COSTLE, Administrator, U.S.
Environmental Protection Agency,
Defendant.

MEMORANDUM

BARRON P. McCUNE, District Judge

Dated: June 12, 1981.

The following is written to comply with Rule 52 following a non jury trial during August and September of 1980.

Plaintiff, in its complaint, mounted a broad attack on the 1978 amendments to the Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C.A. §§136-136y (1980), as well as certain regulations promulgated in 1979 by the Environmental Protection Agency (EPA) to implement the 1978 amendments. It seeks declaratory and injunctive relief from the operation of the challenged portions of FIFRA the EPA's regulatory practice and procedure as set forth in the regulations.

Mobay is a major developer of pesticides and has been for many years. It has spent millions of dollars in research and development and experimentation and analysis. Production of pesticides is essential to the production of food throughout the world. The evaluation and registration of pesticides are essential to the protection of people. How both interests are to be accommodated has occupied the industry and the government for many years. Both interests have long sought an accommodation, but the result achieved thus far has left Mobay, and we suspect many other developers, exasperated and frustrated. As technology improves, more products are developed, but the need for protection increases.

Mobay's complaints are understandable. Certainly a better accommodation can be devised by the human mind, and it must be, if the industry is to succeed in developing the sophisticated pesticides which will be required in the years to come.

However, for the reasons which follow, we cannot grant either declaratory or injunctive relief, in our judgment.

In essence, Mobay attacks three features of FIFRA's new regulatory scheme. *First*, EPA's use of data previously submitted by one applicant to support the application for registration filed by a later applicant. *Second*, disclosure provisions which make certain trade secret data submitted to EPA available to the public and to government contractors. *Third*, EPA's policy of issuing, for the time being, only conditional registrations and of requiring, from time to time, general, as opposed to specific and detailed, data requirements in order to maintain the conditional registrations.

These features of the regulatory scheme, Mobay claims, render research and development in the pesticide

industry unprofitable and impractical. It says that chemical companies will not devote large amounts of money and time to developing new pesticides if they know that their trade secret data will be disclosed to others; if another company may obtain a registration by relying entirely on their data and submitting none of its own; if EPA is continually imposing new conditions on them which they must meet in order to keep their products on the market; or if EPA does not publish definite data requirements specifying exactly what tests and studies must be submitted.

In short, Mobay contends that the scheme is now arbitrary and uncertain.

The defendant offered justification for both the FIFRA amendments and EPA's interpretation of those amendments, expressed in its regulations. The defendant contends that Congress and the EPA acted together to increase competition in the pesticide industry, present all scientific data necessary for informed regulatory decisions before EPA, protect the proprietary rights of data submitters, inform the public about the effects of the chemicals contained in the pesticides, and ease the burden EPA has long borne in processing thousands of applications for registration and analyzing innumerable items of data. In other words, despite FIFRA's and the regulations' seeming inscrutability, and their allegedly appropriative data sharing scheme, and the interminable registration process, Congress and EPA have devised a rational scheme designed to meet several needs and satisfy diverse interests.

Numerous exhibits were introduced at trial, and both sides have filed extensive pretrial and posttrial briefs. These, together with our review of the transcripts of the able direct and cross examination of both sides' witnesses, have facilitated our understanding of FIFRA and the regulations, and our perception of Mobay's objections to them.

THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

Enacted in 1947, the Federal Insecticide, Fungicide, and Rodenticide Act, ch. 125, 61 Stat. 163 (1947), initially provided for a simple and straightforward registration process. An applicant seeking to register his pesticide—or "economic poison" as it was called then, see *id.* §2(a)—was required to file with the Secretary of Agriculture[1] his name and address, the name of the pesticide, a complete copy of the labeling and a statement of all claims made for it, including directions for use, and, if requested by the Secretary, a full description of the tests made and the results thereof upon which the claims were based. *Id.* §4a, 61 Stat. 167. If he deemed it necessary for the effective administration of the Act, the Secretary could require the applicant to submit the complete formula of the pesticide. *Id.* §4b.

The early FIFRA made it unlawful for any person to reveal or use to his own advantage information relative to product formulas, acquired by authority of the Act, *id.* §3c(4), and provided penalties for violations. *Id.* §8, 61 Stat. 170.

The Secretary registered the pesticide if it appeared that its composition was such as to warrant the proposed claims made for it and if it and its labeling and other submitted materials complied with the Act. *Id.* §4b, 61 Stat. 167-68. If the Secretary was dissatisfied with an application, he would notify the applicant of the manner in which the application failed to comply with the Act, and per-

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1. The Department of Agriculture was responsible for overseeing the registration of pesticides until 1970, when the newly created Environmental Protection Agency assumed the responsibility.

mit him to make the necessary corrections. *Id.* §4c, 61 Stat. 168.

The Secretary was authorized to cancel the registration of any pesticide after it had been registered for five years, unless the registrant requested that it be continued in effect. *Id.* §4e. The Secretary was also authorized to cancel a registration at any time on his own motion "[i]n order to protect the public." *Id.* §4c.

FIFRA was virtually reenacted in 1972[2] (and then amended in 1975[3]) as a response to growing public concern about public health and the ecological effects of pesticides. The new FIFRA provided for a more complete registration process and stronger enforcement measures, and heralded a policy of thorough scientific analysis of pesticide chemicals before making them available to the public. Now, under §3(c)(5), not only does an applicant for registration have to show that his pesticide's composition is such as to warrant the proposed claims for it and that its labeling and other submitted materials comply with the Act before he may obtain a registration, but the EPA must also determine that the pesticide will perform its intended function without unreasonable adverse effects on the environment, and that, when used in accordance with widespread and commonly recognized practice, it will not generally cause unreasonable adverse effects on the environment. Federal Environmental Pesticide Control Act of 1972, Pub. L. No. 92-516, §2, 86 Stat. 980-81 (codified at 7 U.S.C.A. §136a(c)(5) (1980)).

Under §3(c)(3), EPA must review the data submitted with an application and, "as expeditiously as possible,"

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2. Federal Environmental Pesticide Control Act of 1972, Pub. L. No. 92-516, 86 Stat. 973.

3. Act of Nov. 28, 1975, Pub. L. No. 94-140, 89 Stat. 751.

either register the pesticide or notify the applicant that his application does not comply with FIFRA. *Id.*, 86 Stat. 980, 7 U.S.C.A. §136a(c)(3).

Under the 1972 amendments, data submitters for the first time were given proprietary rights in their data. Section 10(a) permitted them to mark any portions of their data which they considered to be trade secrets or commercial or financial information, and section 10(b) prohibited the EPA from disclosing those portions.

The amendments affected data submitters' rights in another way. As under the 1947 Act, applicants still had to submit full descriptions of the tests made and the results thereof upon which their claims were based, if they were requested to do so by EPA. But Congress added the following, to what was now §3(c)(1)(D):

> [D]ata submitted in support of an application shall not, without permission of the applicant, be considered by the Administrator in support of any other application for registration unless such other applicant shall have first offered to pay reasonable compensation for producing the test data to be relied upon and such data is not protected from disclosure by section 10(b).

Federal Environmental Pesticide Control Act of 1972, Pub. L. No. 92-516, §2, 86 Stat. 980. The 1975 amendments limited this protection, however, to data submitted on or after January 1, 1970. Act of November 28, 1975, Pub. L. No. 94-140, §12, 89 Stat. 755. If the parties could not agree on the amount and method of payment the EPA could make this determination, with the owner of the data having a right of appeal to a federal district court. But in no event was registration to be delayed pending the determination of reasonable compensation. *Id.*

One final feature of the amended FIFRA is worth noting. The EPA, realizing that pesticides registered

under the 1947 FIFRA had not been subjected to the thorough scientific testing that new products had to undergo, planned to reregister these older pesticides under the stricter standards of the 1972 amendments. This reregistration was to occur by October 21, 1976, four years after the enactment of the 1972 amendments. Federal Environmental Pesticide Control Act of 1972, Pub. L. No. 92-516, §4(c)(2), 86 Stat. 999. This deadline was extended to October 21, 1977, by the 1975 amendments. Act of Nov. 28, 1975 Pub. L. No. 94-140, §4(ii), 89 Stat. 752.

Problems soon developed with the registration process. One problem was that many data submitters took advantage of FIFRA's trade secret provisions and marked their data on file with EPA as trade secrets pursuant to §10(a), thereby relying on §§10(b) and 3(c)(1)(D) to preclude EPA's use of that data to support anyone else's application without their permission. These claims of trade secret protection thus operated to limit the amount of data available for the EPA to use in considering applications for registration, and to thwart the compensation provision of §3(c)(1)(D).

A second problem was that many applications for new pesticides were being denied because they had insufficient data for meeting the stringent standards of the 1972 amendments necessary for a §3(c)(5) finding of no "unreasonable adverse effects on the environment," while similar products registered under the 1947 Act and awaiting reregistration remained on the market. This created a double standard in registration. The incongruity was particularly irksome to an applicant whose rejected pesticide was identical or substantially similar to one on the market.

The third problem grew out of the burden of separately reregistering the previously registered pesticides. Upon reviewing its files during the mid-1970's, EPA discovered that

the data it had were incomplete and unreliable. It realized it could not reregister any registered pesticides until it determined in what respect the data were incomplete. That EPA would have to acquire more data, plus the fact that some 40,000 products had to be reregistered, impressed upon EPA that it would have to adopt a new registration system if it were to execute FIFRA's mandate.

Congress responded to EPA's plight with the 1978 amendments. Federal Pesticide Act of 1978, Pub. L. No. 95-396, 92 Stat. 819. A notable feature of the amendments is the extensive changes made to §3(c)(1)(D). Now, an applicant must file, if requested by EPA, "a full description of the tests made and the results thereof upon which the claims are based, or alternatively, a citation to data that appear in the public literature or that previously had been submitted to the Administrator. . . ." 7 U.S.C.A. §136a(c)(1)(D).

The original data submitter still has proprietary rights in his data which an applicant who is relying on his data must respect, but these rights have been diminished. Congress removed from §3(c)(1)(D) the ability of a data submitter to invoke §10(b) trade secret protection over his data, and has substituted the following (which we paraphrase here, but quote in full below):

1. With respect to pesticides containing new active ingredients that are initially registered after September 30, 1978, data submitted to support the application for the original registration of the pesticide (or an application for an amendment adding a new use to the registration) shall not, without the written permission of the original data submitter, be considered by EPA to support an application by another person for a period of 10 years after EPA first registers the product. §3(c)(1)(D)(i), 7 U.S.C.A. §136a(c)(1)(D)(i). In other words, those who

submit data relative to new chemicals contained in pesticides registered after September 30, 1978, have exclusive use of their data for 10 years after the pesticides are registered.

2. With respect to data submitted after December 31, 1969, and which is not entitled to exclusive use, EPA may, without the permission of the original data submitter, consider any such data in support of another person's application for 15 years following the date the data were originally submitted, but only if the applicant has made an offer to compensate the original data submitter and also submits the offer to EPA, accompanied by evidence of delivery of the offer to the original data submitter. The parties may fix the terms and amounts of compensation by agreement. If they cannot reach an agreement after 90 days, either party may initiate binding arbitration proceedings by asking the Federal Mediation and Conciliation Service to appoint an arbitrator. Federal officials or courts may not review an arbitrator's findings or determinations except for fraud, misrepresentation, or other misconduct. While compensation is being established, registration of the pesticide is not to be delayed. §3(c)(1)(D)(ii), 7 U.S.C.A. §136a(c)(1)(D)(ii).

3. After the expiration of any period of exclusive use and any period for which compensation is required for use of the data, EPA may consider the data in support of another person's application without the permission of the original data submitter and without an offer having been received to compensate the original data submitter. §3(c)(1)(D)(iii), 7 U.S.C.A. §136a(c)(1)(D)(iii).

The trade secret provisions of §10 have also been changed by the 1978 amendments. Section 10(d), 7 U.S.C.A. §136h(d), authorizes the public disclosure of all information concerning the objectives, methodology, re-

sults, or significance of any test performed on or with a pesticide, and of any residue, environmental chemistry, safety, toxicology, metabolism, and fish and wildlife data. The use of any of this data for registration purposes shall be governed by §3(c)(1)(D).

Information that discloses manufacturing or quality control processes, discloses the details of any methods of testing, detecting, or measuring the quantity of deliberately added inert ingredients, or discloses the identity or percentage quantity of any deliberately added inert ingredients, may not be released unless it is necessary to protect against an unreasonable risk of injury to health or the environment. Likewise, information concerning production, distribution, sale, or inventories is nondisclosable except in connection with a public proceeding to determine whether a pesticide or any ingredient causes unreasonable adverse effects on the environment, if disclosure is necessary in the public interest. Before disclosing any of the data described, however, EPA must notify the data submitter of the proposed disclosure, and §10 sets out procedures for contesting it.

Furthermore, disclosures to foreign or multinational pesticide producers, without the data submitter's consent, are unauthorized under §10(g), 7 U.S.C.A. §136h(g). Penalties for unauthorized disclosures of any kind are provided in §10(f), 7 U.S.C.A. §136a(f).

Another public disclosure provision, but which originated in the 1972 reenactment of FIFRA, is found at §3(c)(2)(A), 7 U.S.C.A. §136a(c)(2)(A). Section 3(c)(2)(A) states that within 30 days after the EPA registers a pesticide, it shall make available to the public the data contained in the registration statement, plus such other scientific information EPA deems relevant to its decision. EPA may not disclose information protected by §10.

A final disclosure provision is found at §10(e), 7 U.S.C.A. §136h(e), permitting EPA to disclose trade secret data to contractors with the United States and their employees, if EPA believes disclosure is necessary for the satisfactory performance of work in connection with FIFRA. As a condition to disclosure, however, the contractor must provide adequate security measures.

As for the problem of alleviating the administrative burden of registering new pesticides and reregistering old ones, EPA devised an innovative process. Before the 1978 amendments, EPA usually was considering applications one at a time, and conducting full data reviews for each pesticide end-use product. This meant that sometimes it was analyzing data concerning products with the same active ingredients over and over again, resulting in a duplication of effort. This fact, together with the realization that it would have to reregister 40,000 products in the same manner, necessitated streamlining the registration process.

Under EPA's new process, it is changing its focus from the end-use product to the active ingredients of the end-use product. EPA is developing a generic standard for each active ingredient. It will conduct a review of all data pertinent to a particular active ingredient, and publish a standard detailing its findings and summarizing its position relative to the active ingredient. Essentially, each standard sets out the conditions which products containing that active ingredient must meet if they are to be registered. Thus, a full data review having already been performed when each standard was developed, EPA will be able simply to make registration decisions for end-use products based on the standard. EPA estimates that it will take 10 to 15 years to develop standards for all of the active ingredients, however, so it will be some time before all registered pesticides are reregistered.

The 1978 amendments authorize and facilitate this change of philosophy. Section 3(c)(2)(C), 7 U.S.C.A. §136a(c)(2)(C), provides that EPA shall publish regulations prescribing simplified registration procedures. One of these simplified procedures is described in §3(c)(2)(D), 7 U.S.C.A. §136a(c)(2)(D), which exempts applicants who have purchased a registered pesticide from another producer and propose to formulate it into an end-use product, from submitting or citing safety data relevant to the purchased product, or from offering to pay compensation otherwise required by §3(c)(1)(D) for the use of such data. This is known as the "formulator's exemption."

The 1978 amendments also removed the definite deadline when reregistration is to occur. Cognizant of the reality of the reregistration ordeal awaiting EPA, Congress has said that reregistration now shall occur "in the most expeditious manner practicable." §3(g), 7 U.S.C.A. §136a(g).

Finally, EPA sought to resolve the anomalous situation resulting from applicants being denied registrations for their pesticides because their data were insufficient to satisfy the stringent standards of the 1972 amendments, while pesticides registered before the amendments remain on the market. EPA proposes to *conditionally* register pesticides, upon a showing that allowing each product on the market will not significantly increase the risk of unreasonable adverse effects on the environment already presented by pesticides on the market. In other words, the EPA would not have to make a §3(c)(5) determination that a pesticide would not cause unreasonable adverse effects on the environment before registering it. Rather, the EPA would only have to be satisfied that allowing the pesticide on the market would not *significantly increase the risk* of environmental harm already existing. The registrant would have to submit additional data when EPA

requested it to fulfill the conditions imposed on his registration, but at least he would be able to sell his product. In this way, the double standard will be averted.

The conditional registration authority is found at §3(c)(7), 7 U.S.C.A. §136a(c)(7). Section 3(c)(7) generally states that, notwithstanding §3(c)(5), EPA may conditionally register or amend the registration of a pesticide if sufficient data are submitted, and registering or amending the registration of the pesticide would not significantly increase the risk of any unreasonable adverse effect on the environment.

That EPA might require a §3(c)(7) registrant to submit additional data is to be expected of a registration denominated as being "conditional." Nevertheless, authority for requesting additional data to support registrations—conditional or not—is provided by the 1978 amendments in §3(c)(2)(B), 7 U.S.C.A. §136a(c)(2)(B), 7 U.S.C.A. §136a(c)(2)(B). Once additional data are requested, registrants must provide evidence within 90 days that they are securing the data. Two or more registrants may agree to develop the additional data jointly, and if they cannot agree on the terms of a data development arrangement, any registrant may initiate binding arbitration. As with §3(c)(1)(D), the findings and determination of the arbitrator are not subject to review except for fraud, misrepresentation, or misconduct. By failing to take steps to secure the additional data, cooperate with a joint development arrangement, or abide by an arbitration decision, a registrant may have his registration suspended.[4]

The changes made by the 1978 amendments are reflected in regulations implementing the conditional regi-

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4. The EPA was authorized, as early as the 1972 reenactment, by §3(c)(2)(A) to request additional data. *See* Federal Environmental Pesticide Control Act of 1972, Pub. L. No. 92-516, §2, 86 Stat. 980. Apparently the 1978 amendments were intended to provide detailed procedures for exercising the authority.

stration and data compensation provisions of FIFRA, which EPA published as final and interim final rules, respectively, on May 11, 1979, at 44 Fed. Reg. 27, 932-53 (published at 40 C.F.R. §§162.2(g), 162.7(d)-(e), (g), 162.8, 162.9-1 to 8, 162.18-1 to 5 (1980)). For the purposes of this general discussion, it is necessary only to mention the notable features of the regulations at this time.

Sections 162.9-1 to 8 interpret and implement the compensation provisions of §3(c)(1)(D). It will be recalled that §3(c)(1)(D) gives data submitters certain exclusive use or compensatory rights in their data. Section 3(c)(1)(D) also describes how applicants fulfill their responsibility of submitting data to EPA. Applicants must file a statement which includes,

> if requested by the Administrator, a full description of the tests made and the results thereof upon which the claims are based, or alternatively a citation to data that appears in the public literature or that previously had been submitted to the Administrator. . . .

7 U.S.C.A. §136a(c)(1)(D). EPA has interpreted this provision as requiring an applicant, if no generic standard exists, to rely on all data in EPA's files which concern his product or a similar product, even if the applicant has submitted his own data which he himself has generated. *See* 40 C.F.R. §162.9-4. EPA thus is foreclosing an applicant from exercising what a cursory reading of §3(c)(1)(D) suggests is an option either to submit his own data or to cite data in EPA's files.

This is the so-called "cite all" method of supporting an application.[5] EPA has interpreted §3(c)(1)(D) in this

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5. Once a generic registration standard is published for a particular active ingredient, an applicant need only cite the standard in order to fulfill essentially his data support obligation. *See* 40 C.F.R. §162.9-3.

way because it believes it is consistent with the spirit of FIFRA to require that it have all relevant information in order to determine that a pesticide will not cause unreasonable adverse effects on the environment. EPA says it cannot know if the data which an applicant chooses to give it is sufficient to make this determination.

Of course, those other applicants who submitted the data to EPA upon which the applicant now relies will have to be compensated. Their names and the chemicals for which they submitted data appear on a "Pesticide Data Submitters by Chemical" list. An applicant must examine this list and offer to pay each person listed as a data submitter for that chemical. *See* 40 C.F.R. §162.9-5.

The regulations also provide that EPA will issue, almost exclusively, nothing but conditional registrations under §3(c)(7). *See id.* §162.7(d)-(e). It will issue unconditional registrations under §3(c)(5) only when reregistering currently registered pesticides, when acting on applications for registration of products containing new chemicals, or when it determines that it would otherwise serve the public interest. *Id.* §162.7(d)(1).

MOBAY'S COMPLAINT

Mobay's complaint contains three counts. In Count I of its First Amended Complaint, Mobay asks us (1) to declare that the provisions of §3(c)(1)(D), pertaining the use of its data for its competitors' benefit, constitute a taking without just compensation and violate the fifth amendment; (2) to declare unconstitutional the provision of §3(c)(1)(D) which allegedly compels it to submit to binding arbitration the determination of reasonable compensation for use of its data, upon pain of forfeiture of its registration, and which limits its right to judicial review of that determination; (3) to declare that §3(c)(2)

(B) does not compel it to agree to develop, with other registrants, additional data requested by EPA, or to participate in procedures for reaching agreements concerning joint data development, or to submit to binding arbitration to resolve the problem of reaching agreements concerning joint data development; (4) to declare which registrants are exempted by the formulator's exemption, described in §3(c)(2)(D), from providing safety data or complying with §3(c)(1)(D); and (5) to declare unconstitutional the public disclosure provisions of §§3(c)(2)(A), 10(d), and 10(e), and the prohibition against disclosures to foreign or multinational pesticide producers, set out in §10(g). Mobay also seeks to enjoin EPA from using its trade secret data for other applicants' applications, and from disclosing its trade secret data, both without its express written permission; from otherwise implementing and enforcing §§3(c)(1)(D), 3(c)(2)(A), and 10(d); and from implementing and enforcing §3(c)(2)(B).

In Count II, Mobay seeks declaratory and injunctive relief from EPA's administration of the pesticide registration procedure. It claims that EPA has violated §§3(c)(3) and 3(c)(5) by failing to review data submitted in support of its applciations for registrations and granting it unconditional registrations as expeditiously as possible.

Mobay also challenges the conditional registration and data compensation regulations, alleging that they violate FIFRA and are arbitrary, capricious, and unlawful. In particular, it takes exception to (1) the "cite all" method; (2) EPA's conditional-registration-only policy; (3) EPA's interpretation of the formulator's exemption under §3(c)(2)(D), as expressed in 40 C.F.R. §162.9-7 (1980); and (4) the amendment of §162.8, subsection (b) of which previously had set out data requirements for registration with some detail, but which now requests the submission

of data sufficient for making an incremental risk assessment. Mobay says that the amendment now offers little guidance concerning the data to be submitted.

In addition, Mobay alleges that the regulations are void because EPA did not comply with the procedural requirements of FIFRA and the Administrative Procedure Act, 5 U.S.C. §553 (1976).

Finally, in Count II, Mobay seeks declaratory and injunctive relief with regard to EPA's use or consideration of its trade secret data submitted prior to January 1, 1970, unless Mobay gives its express written permission.

In Count III, Mobay seeks to realize compensation rights from the reregistration of 23 products manufactured by other companies who supported their applications by relying on Mobay's data, but who violated §3(c)(1)(D). A district court in the Western District of Missouri ruled that Mobay would receive compensation when the 23 products were reregistered. *See Mobay Chemical Corp. v. Costle*, 447 F. Supp. 811, 823-24 (W.D. Mo. 1978). That was before §3(g) was added by the 1978 amendments to authorize EPA to reregister pesticides "in the most expeditious manner practicable," however.

In Count III, Mobay seeks a declaratory judgment that as applied to it, §3(g) deprives it of its property without due process or just compensation, in violation of the fifth amendment. It also seeks a judgment ordering EPA to immediately reregister the 23 pesticides, or else to cancel their registrations.

We divide our discussion into three parts. In Part I, we consider the effect of FIFRA on the trade secret data which Mobay has submitted to EPA. In Part II, we examine the registration process derived from the 1978 FIFRA amendments and defined by the compensation and conditional registration regulations. And in Part III, we consider the matter of reregistration.

I

PROVISIONS OF FIFRA AFFECTING MOBAY'S TRADE SECRET DATA

A. *EPA's Use of Mobay's Trade Secret Data to Support Other Applicants' Applications Under §3(c)(1)(D)*

Mobay alleges that the provisions of §3(c)(1)(D), 7 U.S.C.A. §136a(c)(1)(D) (1980),[6] permitting the use

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6. (c) Procedure for Registration.-

(1) Statement required. - Each applicant for registration of a pesticide shall file with the Administrator a statement which includes-

(A) the name and address of the applicant and of any other person whose name will appear on the labeling;

(B) the name of the pesticide;

(C) a complete copy of the labeling of the pesticide, a statement of all claims to be made for it, and any directions for its use;

(D) except as otherwise provided in subsection (c)(2)(D) of this section, if requested by the Administrator, a full description of the tests made and the results thereof upon which the claims are based, or alternatively a citation to data that appears in the public literature or that previously had been submitted to the Administrator and that the Administrator may consider in accordance with the following provisions:

(i) with respect to pesticides containing active ingredients that are initially registered under this Act after September 30, 1978, data submitted to support the application for the original registration of the pesticide, or an application for an amendment adding any new use to the registration and that pertains solely to such new use, shall not, without the written permission of the original data submitter, be considered by the Administrator to support an application by another person during a period of ten years following the date the Administrator first registers the pesticides: Provided, That such permission shall not be required in the case of defensive data;

(ii) except as otherwise provided in subparagraph (D)(i) of this paragraph, with respect to data submitted after December 31, 1969, by an applicant or registrant to support an application for registration, experimental use

(Continued on following page)

of its trade secret data for the benefit of its competitors without its consent, are beyond any power conferred on Congress by the Constitution, and constitute a taking of its property for a private purpose without due process and just compensation, in violation of the fifth amendment. In addition, it objects to the fact that the proprietary rights in its data provided by §3(c)(1)(D) terminate once the limited periods of entitlement to exclusive use or compensation expire.

Footnote continued—

permit, or amendment adding a new use to an existing registration, or for reregistration, the Administrator may, without the permission of the original data submitter, consider any such item of data in support of an application by any other person (hereinafter in this subparagraph referred to as the "applicant") within the fifteen-year period following the date the data were originally submitted only if the applicant has made an offer to compensate the original data submitter and submitted such offer to the Administrator accompanied by evidence of delivery to the original data submitter of the offer. The terms and amount of compensation may be fixed by agreement between the original data submitter and the applicant, or, failing such agreement, binding arbitration under this subparagraph. If, at the end of ninety days after the date of delivery to the original data submitter of the offer to compensate, the original data submitter and the applicant have neither agreed on the amount and terms of compensation nor on a procedure for reaching an agreement on the amount and terms of compensation, either person may initiate binding arbitration proceedings by requesting the Federal Mediation and Conciliation Service to appoint an arbitrator from the roster of arbitrators maintained by such Service. The procedure and rules of the Service shall be applicable to the selection of such arbitrator and to such arbitration proceedings, and the findings and determination of the arbitrator shall be final and conclusive, and no official or court of the United States shall have power or jurisdiction to review any such findings and determination, except for fraud, misrepresentation, or other misconduct by one of the parties to the arbitration or the arbitrator where there is a verified complaint with supporting affidavits attesting to specific instances of such fraud, misrepresentation, or other misconduct. The parties to the arbitration shall share equally in the payment of the fee and expenses of the arbitrator. If the Administrator determines that an original data submitter has failed to par-

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Mobay also challenges §3(c)(1)(D)'s provision for binding arbitration of disputes concerning reasonable compensation owed the original data submitter. It contends that the arbitration scheme violates its liberty of contract and constitutes a taking, in that it denies Mobay the right to a judicial determination of just compensation for the taking of its property.

EPA responds that, even if §3(c)(1)(D) were found to constitute a taking, any taking would be for the public purpose of fostering competition in the pesticide industry. EPA explains that §3(c)(1)(D) prevents a data submitter

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Footnote continued—

ticipate in a procedure for reaching an agreement or in an arbitration proceeding as required by this subparagraph, or failed to comply with the terms of an agreement or arbitration decision concerning compensation under this subparagraph, the original data submitter shall forfeit the right to compensation for the use of the data in support of the application. Notwithstanding any other provision of this Act, if the Administrator determines that an applicant has failed to participate in a procedure for reaching an agreement or in an arbitration proceeding as required by this subparagraph, or failed to comply with the terms of an agreement or arbitration decision concerning compensation under this subparagraph, the Administrator shall deny the application or cancel the registration of the pesticide in support of which the data were used without further hearing. Before the Administrator takes action under either of the preceding two sentences, the Administrator shall furnish to the affected person, by certified mail, notice of intent to take actions and allow fifteen days from the date of delivery of the notice for the affected person to respond. If a registration is denied or canceled under this subparagraph, the Administrator may make such order as the Administrator deems appropriate concerning the continued sale and use of existing stocks of such pesticide. Registration action by the Administrator shall not be delayed pending the fixing of compensation;

(iii) after expiration of any period of exclusive use and any period for which compensation is required for the use of an item of data under subparagraphs (D)(i) and (D)(ii) of this paragraph, the Administrator may consider such item of data in support of an application by any other applicant without the permission of the original data submitter and without an offer having been received to compensate the original data submitter for the use of such item of data.

from relying on §10(b) to impose an indefinite monopoly on his data, a monopoly which would extend well past the 17-year period provided for patents.

As to the issue of just compensation, EPA argues that Mobay may receive just compensation for any taking by filing a suit in the Court of Claims, pursuant to the Tucker Act.[7] Addressing Mobay's contention that its Tucker Act remedy is unavailable by virtue of the existence of binding arbitration for compensation disputes, and the explicit prohibition against seeking judicial review of an arbitrator's determination, EPA notes that Congress has not withdrawn a Tucker Act remedy, *see Regional Rail Reorganization Act Cases*, 419 U.S. 102, 126 (1974), and that, in any event, it is the purpose of §3(c)(1)(D)'s compensation provisions only to provide compensation as between the parties, rather than just compensation from the government.

Finally, EPA denies that §3(c)(1)(D) in fact constitutes a taking. It says that Mobay retains virtually all of its rights in its data. It also asserts that §3(c)(1)(D)'s data consideration scheme represents a reasonable exercise of the government's power to place as much information before it as possible for making informed decisions about pesticides which will affect public health and the environment.

Mobay's challenges to §3(c)(1)(D) raised interesting questions involving the taking clause of the fifth amend-

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7. The Tucker Act, 28 U.S.C. §1491, reads in pertinent part:

The Court of Claims shall have jurisdiction to render judgment upon any claim against the United States founded either upon the Constitution, or any Act of Congress, or any regulation of an executive department, or upon any express or implied contract with the United States, or for liquidated or unliquidated damages in cases not sounding in tort.

ment[8] which both parties had briefed thoroughly, and which had been a major issue during the trial. Since the trial was held, however, the Third Circuit Court of Appeals has decided a case also involving a challenge to §3(c)(1)(D), *Chevron Chemical Co. v. Costle*, 641 F.2d 104 (3d Cir. 1981), *cert. docketed*, No. 80-1680.

Chevron Chemical Company (Chevron) alleged that use by the EPA of its pre-1970 data was an uncompensated taking in violation of the fifth amendment. It also contended that use by the EPA of its post-1969 data to support other applicants' applications was a taking for private rather than public purposes, and that the binding arbitration provision deprived it of an opportunity for a judicial determination of just compensation.

The court of appeals did not reach the question whether §3(c)(1)(D) took Chevron's property, in violation of the fifth amendment, because it determined that Chevron essentially had no property in the first place. The district court in *Chevron* assumed that Chevron's trade secret data were property, and EPA in this case was willing to assume that Mobay's trade secret data likewise were property. Nevertheless, it is clear that a threshold determination must be made whether the subject matter of an alleged taking is "property" within the meaning of the fifth amendment.

The court of appeals held that a property right arises out of an entitlement created by some law. *Id.* at 114, *citing Paul v. Davis*, 424 U.S. 693 (1976), *Meachum v. Fano*, 427 U.S. 215 (1976), and *Montayne v. Haymes*, 427 U.S. 236 (1976). Federal statutory law may protect intellectual property, but it can not preempt state law, which traditionally has protected it.

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8. *See* Note, *FIFRA and the "Taking" of Trade Secrets*, 8 Boston College Envt'l Affairs L. Rev. 593 (1980).

The court of appeals noted that the 1972 amendment of FIFRA, adding §3(c)(1)(D), conferred a property right in some data submitted to EPA. But that only provided protection from the date when the 1972 amendments became effective. Before that time, the only other pertinent federal statute was 18 U.S.C. §1905, which provides criminal penalties for the unauthorized disclosure of trade secret data by federal officers or employees. The court observed, however, that criminal statutes are rarely construed as conferring a private right of action. *Id.* at 115, *citing Chrysler Corp. v. Brown*, 441 U.S. 281, 316-17 (1979). At best, the court believed that 18 U.S.C. §1905 created a federal law right of non-disclosure, not of non-use by a federal agency. *Id.*

Finding no federal statute, the court then searched for any state law purporting to confer a state law property interest in data Chervon had voluntarily submitted to a federal agency. Chevron proffered only Restatement of Torts §757 (1939), which provides civil liability for the nonprivileged disclosure or use of trade secrets.[9] But the court observed that this provision also dealt with the disclosure of trade secrets to others, rather than use of trade secrets by a government agency.[10] *Id.* The court recog-

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9. Section 757 provides, in pertinent part:

One who discloses or uses another's trade secret, without a privilege to do so, is liable to the other if

(a) he discovered the secret by improper means, or

(b) his disclosure or use constitutes a breach of confidence reposed in him by the other in disclosing the secret to him. . . .

10. The fact that §757(b) also imposes liability for unauthorized use of trade secrets suggests that it provides a right of non-use by a government agency. The court of appeals discounted this interpretation, although it did not specifically discuss subsection (b). The court believed that §757's concern was with using improper means to obtain trade secrets and using them to advance the business of the owner's competitors. 641 F.2d at 115-16. *See also* Restatement of Torts, §757, comment a at 3-4, comment c at 8-9, comment j at 13-14 (1939); *id.* §759.

nized that Chevron undoubtedly had submitted its data to EPA and its predecessors with some expectation of privacy. But it held that 18 U.S.C. §1905 and agency practice[11] had defined the scope of that expectation prior to the 1972 FIFRA amendments, and that, since that time, the various versions of §3(c)(1)(D) had done so. *Id.*

In any event, the court expressed doubt that a state law defining the degree of confidentiality in which federal agencies must keep information submitted to them in connection with their regulatory responsibilities, if it existed, would survive supremacy clause scrutiny. *Id.* at 116.

The court of appeals therefore held that Chevron had no property right in its data until the 1972 amendments created §3(c)(1)(D). And the 1975 amendment of §3(c)(1)(D), to provide compensation for reliance on data submitted after 1969, subsequently enlarged the property right to extend from January 1, 1970, onward. Nevertheless, despite the fact that Chevron did have a property interest in some of its data, the court of appeals held that "Congress, having conferred a property right to which the chemical companies had no prior claims, may condition that right to accommodate agency practice." *Id.* at 117 n.29.

Thus, the *Chevron* case must be read as authorizing EPA's use, without the original data submitter's permission,

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11. No trial had been held in the *Chevron* case, as the district court granted EPA's motion for summary judgment, see *Chevron Chemical Co. v. Costle*, 499 F. Supp. 732 (D. Del. 1980), and Chevron was appealing from the order granting that motion. We had the opportunity to learn firsthand the practices of EPA and the Department of Agriculture respecting agency use of submitted data. Dr. Harold G. Alford, who was closely involved with the pesticide registration process while at EPA and USDA from 1961 through 1972, testified that at least from 1967 to 1970 it was the practice of the agencies to require applicants to obtain authorization from original data submitters only for relying on confidential statements of formula. Dr. Alford testified there was no requirement that an applicant obtain authorization to rely on data other than the formula.

of data submitted before 1970. It also must be read as authorizing EPA's use of data submitted after 1969, but in conformity with the compensation and exclusive use provisions of §3(c)(1)(D) which were added by the 1978 amendments. Because we find that Chevron and Mobay's challenges to §3(c)(1)(D) are identical, we deny Mobay relief in connection with its contention that the use of its trade secret data to support applications by third parties under §3(c)(1)(D) constitutes a taking in violation of the fifth amendment.

Like Mobay, Chevron had also challenged the binding arbitration scheme provided by §3(c)(1)(D) for resolving compensation disputes involving the use of post-1969 data. The district court ruled that the language of §3(c)(1)(D) indicated that that section was intended to provide for the payment of compensation by a private entity, and not just compensation from the government if a taking occurred. 449 F. Supp. at 743. The district court observed that an arbitration scheme between private parties could not be viewed as precluding resort to the Court of Claims. As a result, the district court concluded that Chevron's Tucker Act remedy had not been withdrawn. *Id.* *See Regional Rail Reorganization Act Cases*, 419 U.S. 102, 126 (1974).

The court of appeals did not disagree with the district court's interpretation of the *Regional Rail Reorganization Act Cases*. But it held that it was unnecessary to consider whether a Tucker Act remedy was available, since it found no property interest beyond that conferred by 18 U.S.C. §1905 and §3(c)(1)(D), and hence there was no taking for which such a remedy was needed. 641 F.2d at 116-17.

Since Mobay's challenge to the arbitration scheme is similar to Chevron's, we find that this portion of §3(c)(1)

(D) is valid and Mobay is not entitled to declaratory or injunctive relief.

Mobay further claims that the allegedly compulsory binding arbitration scheme violates its liberty of contract. We disagree. First, arbitration comes into play only when Mobay and an applicant seeking to rely on its data cannot reach an agreement after 90 days on the terms and amount of compensation or on a procedure for reaching such an agreement, and either Mobay or the applicant requests arbitration.

Second, EPA has published rules controlling the arbitration procedure. *See* 29 C.F.R. §1440.1 (1980).[12] Under FIFRA and the regulations, the rules of the Federal Mediation and Conciliation Service apply to the selection of the arbitrator and to the arbitration proceedings. The arbitrators are to be selected from the roster of commercial arbitrators maintained by the American Arbitration Association.

Thus, EPA has supplied the arbitration procedure with detailed rules designed to provide guidance and ensure fairness, and has staffed it with arbitrators who are knowledgeable in commercial matters. Binding arbitration is not the exclusive means for determining reasonable compensation, but is to be used only after other methods have failed to reach an agreement. We find that the FIFRA arbitration scheme does not violate Mobay's liberty of contract.

Accordingly, we deny Mobay's request for declaratory and injunctive relief from §3(c)(1)(D)'s provision for binding arbitration to settle data compensation disputes.

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12. These procedures were published as final rules on April 28, 1980, at 45 Fed. Reg. 28,107. They were published in a notice of proposed rulemaking on July 24, 1979, at 44 Fed. Reg. 43,292-98.

B. *Trade Secret Data Disclosure Provisions Under §§3(c)(2)(A) and 10*

1. *Public Disclosure Under §§3(c)(2)(A) and 10(d)*

Section 3(c)(2)(A), 7 U.S.C.A. §136a(c)(2)(A), provides that within 30 days after EPA registers a pesticide, it shall make available to the public the data called for in the registration statement, together with such other scientific information as it deems relevant to its decision. Disclosure is subject to the trade secret provisions of §10, 7 U.S.C.A. §136h.

Section 10, as mentioned earlier, permits data submitters to mark portions of their data which they consider to be trade secrets and, until the 1978 amendments, generally prohibited the EPA from disclosing such data to the public. The 1978 amendments qualified this prohibition, however. Now, under §10(d)(1)-(2), 7 U.S.C.A. §136h(d)(1)-(2),

(d) Limitations.—

(1) All information concerning the objectives, methodology, results, or significance of any test or experiment performed on or with a registered or previously registered pesticide or its separate ingredients, impurities, or degradation products, and any information concerning the effects of such pesticide on any organism or the behavior of such pesticide in the environment, including, but not limited to, data on safety to fish and wildlife, humans and other mammals, plants, animals, and soil, and studies on persistence, translocation and fate in the environment, and metabolism, shall be available for disclosure to the public: Provided, That the use of such data for any registration purpose shall be governed by section 3 of this

Act: Provided further, That this paragraph does not authorize the disclosure of any information that—

(A) discloses manufacturing or quality control processes,

(B) discloses the details of any methods for testing, detecting, or measuring the quantity of any deliberately added inert ingredient of a pesticide, or

(C) discloses the identity or percentage quantity of any deliberately added inert ingredient of a pesticide, unless the Administrator has first determined that disclosure is necessary to protect against an unreasonable risk of injury to health or the environment.

(2) Information concerning production, distribution, sale, or inventories of a pesticide that is otherwise entitled to confidential treatment under subsection (b) of this section may be publicly disclosed in connection with a public proceeding to determine whether a pesticide, or any ingredient of a pesticide, causes unreasonable adverse effects on health or the environment, if the Administrator determines that such disclosure is necessary in the public interest.

Section 10(d)(3), 7 U.S.C.A. §136h(d)(3), provides that data submitters must receive notice of proposed disclosures under 10(d)(1) (A), (B), or (C), or §10(d)(2), and may challenge proposed disclosures in district court.[13] It bears

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13. (3) If the Administrator proposes to disclose information described in clause (A), (B), or (C) of paragraph (1) or in paragraph (2) of this subsection, the Administrator shall notify by certified mail the submitter of such information of the intent to release such information. The Administrator may not release such information, without the submitter's consent, until thirty days after the submitter has been furnished such notice: Provided, That where the Administrator

(Continued on following page)

observing that the use of any data, which has been released under §10(d), for registration purposes shall be governed by §3(c)(1)(D).

Mobay alleges in Count I that §§3(c)(2)(A) and 10(d) are beyond the power conferred on Congress by the Constitution, and that they constitute a taking without just compensation and due process of law, in violation of the fifth amendment. EPA argues that these sections represent a reasonable exercise of the police power designed to inform the public about the hazardous effects of toxic pesticides which are available on the market for purchase and use.

We note at the outset that §§3(c)(2)(A) and 10(d), being duly enacted by Congress, constitute "authorization by law" which precludes the criminal sanctions of 18 U.S.C. §1905.

The legislative history of FIFRA is replete with evidence of Congress' concern that the public be informed

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Footnote continued—

finds that disclosure of information described in clause (A), (B), (C) of paragraph (1) of this subsection is necessary to avoid or lessen an imminent and substantial risk of injury to the public health, the Administrator may set such shorter period of notice (but not less than ten days) and such method of notice as the Administrator finds appropriate. During such period the data submitter may institute an action in an appropriate district court to enjoin or limit the proposed disclosure. The court shall give expedited consideration to any such action. The court may enjoin disclosure, or limit the disclosure or the parties to whom disclosure shall be made, to the extent that —

(A) in the case of information described in clause (A), (B), or (C) of paragraph (1) of this subsection, the proposed disclosure is not required to protect against an unreasonable risk of injury to health or the environment; or

(B) in the case of information described in paragraph (2) of this subsection, the public interest in availability of the information in the public proceeding does not outweigh the interests in preserving the confidentiality of the information.

about the rationale for an agency decision to register a pesticide, and that they be able to evaluate most of the data supporting that decision. But there is also evident a concern that trade secrets not be unduly compromised.

With the addition of §10(d),[14] FIFRA joins other recent federal statutes which also provide for the disclosure of trade secret data submitted to the government. *See, e.g.*, 15 U.S.C. §2613 (Toxic Substances Control Act); 42 U.S.C. §7607(a)(1) (emission data under the 1977 amendments to the Clean Air Act); 42 U.S.C. §300j-4(d) (data concerning level of contaminants under the Safe Drinking Water Act).

We believe that §§3(c)(2)(A) and 10(d) violate neither due process nor the taking clause of the fifth amendment. The Supreme Court made it clear long ago in *National Fertilizer Association v. Bradley*, 301 U.S. 178 (1937), and *Corn Products Refining Co. v. Eddy*, 249 U.S. 427 (1919), that

> it is too plain for argument that a manufacturer or vendor has no constitutional right to sell goods without giving to the purchaser fair information of what it is that is being sold. The right of a manufacturer to maintain secrecy as to his compounds and processes must be held subject to the right of the State, in the exercise of its police power and in promotion of fair dealing, to require that the nature of the product be fairly set forth.

Corn Products Refining Co. v. Eddy, *supra*, 249 U.S. at 431-32; *National Fertilizer Association v. Bradley*, *supra*, 301 U.S. at 182. These cases held that state laws requiring manufacturers of syrup and fertilizer, respectively, to put

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14. Section 3(c)(2)(A)'s data disclosure provision was added by the 1972 amendments. Since disclosure under §3(c)(2)(A) is subject to §10, its validity stands or falls with that of §10(d).

labels on their containers disclosing the percentages of ingredients, did not violate the due process clause of the fourteenth amendment. The manufacturers had complained that the laws forced them to divulge their trade secret formulas, and thus deprived them of their property.

As to Mobay's allegation that the disclosure provisions constitute an unlawful taking of their property, we refer to the Third Circuit decision in *Westinghouse Electric Corp. v. United States Nuclear Regulatory Commission*, 555 F.2d 82 (3d Cir. 1977). In that case, the court of appeals upheld a Nuclear Regulatory Commission regulation making information submitted in connection with NRC's licensing procedure available for public inspection or disclosure, except when a balancing of the interests of the data submitter urging nondisclosure, and the public interest in disclosure, compelled a different result.

The Third Circuit explicitly rejected Westinghouse Electric's contention that the regulation authorized a taking of its data without compensation in violation of the fifth amendment. *Cf. Utah Fuel Co. v. National Bituminous Coal Commission*, 306 U.S. 56 (1939) (upholding an order of the Commission issued pursuant to the Bituminous Coal Act of 1937, directing the publication of certain costs and sales realization data furnished by producers; the Court said, *id.* at 61-62, that "[o]bviously publication may be harmful to petitioners but as Congress had adequate power to authorize it and has used language adequate thereto we can find here no sufficient basis for an injunction.")

Thus, we hold that §§3(c)(2)(A) and 10(d) are within Congress' police power, and do not violate the due process or taking clauses of the fifth amendment. We therefore deny Mobay's request for relief as to that portion of Count I challenging those sections.

2. *Disclosure to Government Contractors Under §10(e)*

Mobay also challenges in Count I the provisions of §10(e), 7 U.S.C.A. §136h(e),[15] which permits EPA to disclose trade secret data to contractors with the United States, and to employees of the contractors, if disclosure is necessary for the satisfactory performance of a contract in connection with FIFRA. Disclosure is contingent upon the contractor providing security precautions to protect the data's confidentiality.

Mobay alleges that EPA has not yet promulgated regulations with respect to these security precautions. It argues that disclosure to contractors without adequate safeguards denies it due process of law in violation of the fifth amendment.

EPA concedes that it has not promulgated regulations implementing §10(e). (According to James Nelson, a witness for EPA, EPA has not published final regulations because it is awaiting the outcome of this case and other litigation challenging the 1978 amendments.) But it points to the fact that it published a notice of interim procedures in 1978, which generally adopted the procedures described in EPA's regulations implementing the Freedom of Information Act. 43 Fed. Reg. 59,060, 59,062 (1978). Among

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15. (e) Disclosure to Contractors. — Information otherwise protected from disclosure to the public under subsection (b) of this section may be disclosed to contractors with the United States and employees of such contractors if, in the opinion of the Administrator, such disclosure is necessary for the satisfactory performance by the contractor of a contract with the United States for the performance of work in connection with this Act and under such conditions as the Administrator may specify. The Administrator shall require as a condition to the disclosure of information under this subsection that the person receiving it take such security precautions respecting the information as the Administrator shall by regulation prescribe.

these procedures is the requirement that the data submitter be given advance notice of the proposed disclosure, and that the contract contain a specific clause restricting the use and disclosure of the data. *Id.* In addition, the EPA indicated in the notice that it will also follow procedures already set out for disclosures to contractors performing work in connection with the Toxic Substances Control Act. *Id.*

EPA also notes that §10(f), 7 U.S.C.A. §136h(f), provides penalties for unauthorized disclosures of trade secret data obtained by contractors or their employees.

We find that these procedures, even though not promulgated in final form, are adequate to protect the confidentiality of Mobay's data. By reference, they incorporate safeguards found in other regulations which have gone unchallenged. In the absence of any contrary evidence, we cannot say that the safeguards provided are inadequate. *United States v. Westinghouse Electric Corp.*, 638 F.2d 570, 579-80 (3d Cir. 1980).

We therefore deny Mobay's request for relief as to §10(e).

3. *Prohibition of Disclosure to Foreign and Multinational Pesticide Producers Under §10(g)*

Section 10(g), 7 U.S.C.A. §136h(g),[16] prohibits EPA from knowingly disclosing data to any employee or agent

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16. (g) Disclosure to Foreign and Multinational Pesticide Producers.—

(1) The Administrator shall not knowingly disclose information submitted by an applicant or registrant under this Act to any employee or agent of any business or other entity engaged in the production, sale, or distribution of pesticides in countries other than the United States or in addition to the United States or to any other person who intends to deliver

(Continued on following page)

of a business or entity engaged in the production, sale, or distribution of pesticides in countries other than or in addition to the United States, or to a person who intends to deliver the data to such a business or entity. If the data submitter consents, the EPA may disclose the data.

Mobay argues that §10(g) deprives it of its property without due process of law, and denies it equal protection of the laws. It asserts that the practical effect of §10(g) is to permit disclosure of its data to companies doing business solely in the United States, but to deny disclosure of their data to it because it is a multinational corporation. Mobay contends that there is no reasonable or rational basis for distinguishing between multinational and foreign companies, and companies selling pesticides solely in the United States.

Footnote continued—

such data to such foreign or multinational business or entity unless the applicant or registrant has consented to such disclosure. The Administrator shall require an affirmation from any person who intends to inspect data that such person does not seek access to the data for purposes of delivering it or offering it for sale to any such business or entity or its agents or employees and will not purposefully deliver or negligently cause the data to be delivered to such business or entity or its agents or employees. Notwithstanding any other provision of this subsection, the Administrator may disclose information to any person in connection with a public proceeding under law or regulation, subject to restrictions on the availability of information contained elsewhere in this Act, which information is relevant to the determination by the Administrator with respect to whether a pesticide, or any ingredient of a pesticide, causes unreasonable adverse effects on health or the environment.

(2) The Administrator shall maintain records of the names of persons to whom data are disclosed under this subsection and the persons or organizations they represent and shall inform the applicant or registrant of the names and affiliation of such persons.

(3) Section 1001 of title 18 of the United States Code shall apply to any affirmation made under paragraph (1) of this subsection.

Mobay also contends that §10(g) will be ineffectual in preventing foreign or multinational pesticide producers from obtaining copies of its data, in that they can use third parties to make requests for desired data. Mobay says that §10(g) will be unenforceable, because disclosure to the public under the general disclosure provisions of §10(d) will result in almost instantaneous dissemination to foreign or multinational producers. Finally, Mobay says that §10(g) does not provide a definition of "foreign and multinational pesticide producers."

EPA responds to Mobay's equal protection challenge by arguing that §10(g) was enacted to prevent foreign or multinational pesticide producers from obtaining trade secret data from EPA, and using it to support registrations in other countries whose pesticide laws do not provide for compensation of the original data submitter, as FIFRA's §3(c)(1)(D) does.

Section 10(g) creates two classes: the class of pesticide producers engaged in the production, sale, or distribution of pesticides in countries other than the United States or in addition to the United States, and the class of pesticide producers engaged in the production, sale, or distribution of pesticides solely in the United States. In making an equal protection analysis, a court should not overturn a statutory classification "unless the varying treatment of different groups or persons is so unrelated to the achievement of any combination of legitimate purposes that [it] can only conclude that the legislature's actions were irrational." *Vance v. Bradley*, 440 U.S. 93, 97 (1979).[17]

17. Mobay does not suggest, and we do not find, that §10(g) creates a "suspect classification" requiring us to apply a stricter standard of review and determine that the government is pursuing a compelling end.

There is a concern evident in the legislative history of §10(g) that data released under FIFRA's public disclosure provisions might be used to support registrations in other countries. For example, the National Agricultural Chemicals Association, whose members are pesticide producers and sellers, introduced its own proposal for public disclosure at hearings before the House Committee on Agriculture in 1977:

> A registrant, in submitting test data, should be authorized to provide for public inspection a reasonably detailed summary of the data, and mark as confidential the details of the test data.
>
> This would protect the details of the test data from being copied and used without authorization by others *for the purpose of obtaining foreign registrations.*

Federal Insecticide, Fungicide, and Rodenticide Act: Hearings Before the House Comm. on Agriculture, 95th Cong., 1st Sess. 227 (1977) (statement of Jack Early) (emphasis added).

Later the NACA submitted proposed principles, one of which was the following:

> It is recognized that there is a legitimate interest by segments of the public to know and appraise the data upon which registration is based. However, mandatory disclosure of the entire data could cause substantial competitive harm.
>
> For example, it could be used by competitors for foreign registration.

Extending and Amending FIFRA: Hearings Before the Subcomm. on Department Investigations, Oversight, and Research of the House Comm. on Agriculture, 95th Cong.,

1st Sess. 465 (1977) (statement of Jack E. Early). *See also id.* at 192, 482.

Section 10(g) was initially proposed in the House of Representatives by H.R. 8681, 95th Cong., 1st Sess. (1977). The House Report accompanying it said that §10(g) would "[p]rohibit disclosure of any data submitted to the Environmental Protection Agency under the act to any employee or agent of a business entity engaged in production, sale, or distribution of pesticides in countries other than the United States." H.R. Rep. No. 95-663, 95th Cong., 2d Sess. 16, *reprinted in* [1978] U.S. Code Cong. & Ad. News 1966, 1989. The House provision was adopted by the conference committee, with the modification providing for disclosure in connection with public proceedings. H. Conf. Rep. No. 95-1560, 95th Cong., 2d Sess. 40, *reprinted in* [1978] U.S. Code Cong. & Ad. News 1966, 2056.

Thus, it is apparent that §10(g) was enacted to allay the fears of pesticide producers that data released under §10(d) would be used for registration purposes in other countries. That Congress might have drawn a more inclusive classification is irrelevant. "[P]erfection is by no means required." *Vance v. Bradley, supra,* 440 U.S. at 108. So long as the enactment in question has a rational and reasonable basis, we cannot say that Congress should have chosen a means "more precisely related to its primary purpose." *Id.* at 109.

Consequently, we hold that §10(g) does not deny Mobay equal protection of the law.

We next address Mobay's due process challenges to §10(g). EPA points out that, when read together, §§10 (g) and 10(f) impose criminal penalties for unauthorized disclosures, and do not preempt the exercise of civil remedies. Furthermore, the person to whom data is disclosed

is criminally liable for delivering the data to foreign or multinational pesticide producers, in violation of his affirmation that he will not do so. §10(g)(3), 7 U.S.C.A. §136h(g)(3).

Of course, these after-the-fact penalties are little consolation to a data submitter who believes his trade secrets have been compromised. Nevertheless, a data submitter may take measures to prevent this from occurring. The EPA's Notice of Interim Procedures, published at 43 Fed. Reg. 59,060 (1978), provides that data submitters must receive advance notice of proposed disclosures before the requested data may be disclosed to the public under §10(d).[18] Once a data submitter receives notice of a proposed disclosure, it may seek judicial review of that decision to disclose. *Id.* at 59,062. *See* §10(d)(3), 7 U.S.C.A. §136h(d)(3).

We believe that these procedures are the best protection an information-disclosure statute can provide for minimizing the chance that foreign or multinational pesticide producers will obtain Mobay's data. There must be balanced against Mobay's interest in the confidentiality of data it submits to the government, the public's interest in being informed about the effects of pesticides on public health and the environment.

We do not believe that the absence of a specific definition of "foreign and multinational pesticide producer" is violative of due process. Section 10(g) explicitly applies to businesses or entities "engaged in the production, sale, or distribution of pesticides in countries other than the United States or in addition to the United States."

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18. The Notice of Interim Procedures adopts and modifies EPA's regulations implementing the Freedom of Information Act. Generally, data submitters must receive 30 days advance notice of a proposed disclosure. 43 Fed. Reg. at 59,062.

Having determined that §10(g) does not deny Mobay due process or equal protection of the law, we therefore deny its request for relief in Count I as to §10(g).

C. *EPA Requests for Additional Data Under §3(c)(2)(B)*

Section 3(c)(2)(B), 7 U.S.C.A. §136a(c)(2)(B),[19] authorizes EPA to obtain additional data from registrants to

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19. (B) Additional data to support existing registrations.—

(i) If the Administrator determines that additional data are required to maintain in effect an existing registration of a pesticide, the Administrator shall notify all existing registrants of the pesticide to which the determination relates and provide a list of such registrants to any interested person.

(ii) Each registrant of such pesticide shall provide evidence within ninety days after receipt of notification that it is taking appropriate steps to secure the additional data that are required. Two or more registrants may agree to develop jointly, or to share in the cost of developing, such data if they agree and advise the Administrator of their intent within ninety days after notification. Any registrant who agrees to share in the cost of producing the data shall be entitled to examine and rely upon such data in support of maintenance of such registration.

(iii) If, at the end of sixty days after advising the Administrator of their agreement to develop jointly, or share in the cost of developing, data, the registrants have not further agreed on the terms of the data development arrangement or on a procedure for reaching such agreement, any of such registrants may initiate binding arbitration proceedings by requesting the Federal Mediation and Conciliation Service to appoint an arbitrator from the roster of arbitrators maintained by such Service. The procedure and rules of the Service shall be applicable to the selection of such arbitrator and to such arbitration proceedings, and the findings and determination of the arbitrator shall be final and conclusive, and no official or court of the United States shall have power or jurisdiction to review any such findings and determination, except for fraud, misrepresentation, or other misconduct by one of the parties to the arbitration or the arbitrator where there is a verified complaint with supporting affidavits attesting to specific instances of such fraud, misrepresentation, or other misconduct. All parties to the arbitration shall share equally in the payment of the fee and expenses of the arbitrator.

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maintain their registrations in effect, if it believes more information is necessary. Two or more registrants may agree to develop the data jointly, and if they cannot agree

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Footnote continued—

(iv) Notwithstanding any other provision of this Act, if the Administrator determines that a registrant, within the time required by the Administrator, has failed to take appropriate steps to secure the data required under this subparagraph, to participate in a procedure for reaching agreement concerning a joint data development arrangement under this subparagraph or in an arbitration proceeding as required by this subparagraph, or to comply with the terms of an agreement or arbitration decision concerning a joint data development arrangement under this subparagraph, the Administrator may issue a notice of intent to suspend such registrant's registration of the pesticide for which additional data is required. The Administrator may include in the notice of intent to suspend such provisions as the Administrator deems appropriate concerning the continued sale and use of existing stocks of such pesticide. Any suspension proposed under this subparagraph shall become final and effective at the end of thirty days from receipt by the registrant of the notice of intent to suspend, unless during that time a request for hearing is made by a person adversely affected by the notice or the registrant has satisfied the Administrator that the registrant has complied fully with the requirements that served as a basis for the notice of intent to suspend. If a hearing is requested, a hearing shall be conducted under section 6(d) of this Act: Provided, That the only matters for resolution at that hearing shall be whether the registrant has failed to take the action that served as the basis for the notice of intent to suspend the registration of the pesticide for which additional data is required, and whether the Administrator's determination with respect to the disposition of existing stocks is consistent with this Act. If a hearing is held, a decision after completion of such hearing shall be final. Notwithstanding any other provision of this Act, a hearing shall be held and a determination made within seventy-five days after receipt of a request for such hearing. Any registration suspended under this subparagraph shall be reinstated by the Administrator if the Administrator determines that the registrant has complied fully with the requirements that served as a basis for the suspension of the registration.

(v) Any data submitted under this subparagraph shall be subject to the provisions of subsection (c)(1)(D) of this section. Whenever such data are submitted jointly by two or more registrants, an agent shall be agreed on at the time of the joint submission to handle any subsequent data compensation matters for the joint submitters of such data.

on the terms of a data development arrangement, any registrant may initiate binding arbitration. The arbitration procedure is similar to that of §3(c)(1)(D). The arbitrator's findings and determination are not subject to review except for fraud, misrepresentation, or misconduct. By failing to take steps to secure the additional data, cooperate with a joint data development arrangement, or abide by an arbitrator's decision, a registrant may have his registration suspended. All additional data submitted are subject to §3(c)(1)(D).

In its complaint, Mobay seeks a declaratory judgment that §3(c)(2)(B) does not obligate it to agree to develop additional data jointly with others, or to share in the cost of developing data. It also alleges that the binding arbitration provisions deprive it of its liberty of contract, encroach upon the judiciary, and deprive it of due process, all in violation of the fifth and ninth amendments. Finally, it seeks injunctive relief from the implementation of §3(c)(2)(B).

By stipulation filed August 25, 1980, Mobay and EPA agreed that §3(c)(2)(B) does not compel Mobay to enter into joint data development or cost sharing arrangements with other registrants, and that the arbitration provisions are applicable only if Mobay elects to enter into such arrangements. They also agreed that the standards of §3(c)(2)(A), by which EPA shall publish guidelines specifying the kinds of information required to support registration, are applicable to the data requested under §3(c)(2)(B).

As a result of this stipulation, Mobay deleted the sections of Count I in its complaint which challenged §3(c)(2)(B). In its posttrial brief, however, Mobay asserts that at trial, EPA offered evidence tending to show that it was, in fact, compelling registrants to enter into data developing and cost sharing arrangements. Mobay asks us

to clearly set forth in this opinion the terms of their stipulation.

The evidence to which Mobay apparently refers is Defendant's Exh. No. 18. Marcia Williams, a witness for EPA, was questioned on direct examination about this exhibit, which is a form letter dated March 26, 1980, from EPA notifying registrants of a need for additional data to support the registration of products containing isocyanurates. The letter sets out the options registrants may exercise to submit the additional data, such as generating the data themselves or entering into joint data development arrangements with other registrants.

On page 12 of Exh. No. 18, EPA states that if a registrant attempts to develop the data with another registrant, and has made a bona fide offer to share in the expenses, but the other registrant without good cause rejects this offer, EPA will not suspend the registration of the rebuffed registrant.

We fail to see how the letter can be read to compel registrants to enter into data development arrangements. In fact, in two places it explicitly states that §3(c)(2)(B) does not compel such arrangements. We read this page as an expression of EPA's belief that such arrangements are in the public interest, and that the rebuffed registrant should not have "to engage in economically inefficient duplicative testing in order to maintain its registration."[20]

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20. Mobay alleges that Ms. Williams' testimony suggested that the first registrant need only submit an offer to the second registrant to obtain exemption from suspension, and that the amount of compensation owed the second registrant would be determined under the allegedly "mandatory" arbitration provisions. This is not so. The subject of arbitration arose only in connection with the question of how EPA would determine whether the first registrant's offer was indeed bona fide, and not unrealistically low. Ms. Williams testified that she was unsure how this determination could be made, but she suggested that arbitration could be one solution. We understand her not to be referring to the binding arbitration procedure under §3(c)(2)(B).

Mobay also alleges that EPA may not request additional data under §3(c)(2)(B) until it first publishes guidelines specifying the kinds of information which will be required to support a registration. Plaintiff's Proposed Conclusion of Law No. 24. It relies on §3(c)(2)(A), which reads in pertinent part:

> The Aministrator shall publish guidelines specifying the kinds of information which will be required to support the registration of a pesticide and shall revise such guidelines from time to time. If thereafter he requires any additional kind of information under subparagraph (B) of this paragraph, he shall permit sufficient time for applicants to obtain such additional information.

Mobay's argument is that since EPA has not yet published these guidelines, it may not request additional data.[21]

EPA, in fact, has not published registration data guidelines pursuant to §3(c)(2)(A), at least in final form. It has, however, published proposed guidelines, which EPA says it considers as a general statement of policy regarding the nature and extent of the data required to support registration. *See* 43 Fed. Reg. 29,696 (1978); 43 Fed. Reg. 37,-336 (1978); 45 Fed. Reg. 72,948 (1980). Until the guidelines are published in final form, the information required will be determined on a case-by-case basis. *Id.*

We do not read §3(c)(2)(A) literally, so that the authority for requesting additional data under §3(c)(2)(B) is contingent upon EPA's first publishing data guidelines. Section 3(c)(2)(A) contemplates a situation in which specific data guidelines are available to an applicant seeking registration of a new pesticide. The applicant ex-

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21. Mobay does not ask us to compel EPA to publish these guidelines in final form.

amines the guidelines, submits the required data, and obtains a registration. If EPA later discovers evidence which raises questions about a pesticide's safety, it may request, pursuant to §3(c)(2)(B), that additional data be submitted.

Section 3(c)(2)(A) applies to applications for registration submitted after the date of its enactment, which was October 21, 1972. It thus cannot apply to registrations issued before that time under the 1947 FIFRA, since data guidelines would be unnecessary for already registered pesticides. Under Mobay's interpretation, however, EPA's authority for requesting additional data from pre-1972 FIFRA registrants would be unclear.

If Mobay's interpretation of §3(c)(2)(A) controlled, it would frustrate the operation of §3(c)(2)(B), which we believe must be independent of §3(c)(2)(A). Section 3(c)(2)(B) authorizes requests for additional data "to maintain in effect an *existing registration* of a pesticide." EPA should not be prevented from obtaining data concerning a pesticide to aid it in ascertaining that the pesticide is safe, merely because it has not yet published final data guidelines.

As to the portion of Count I challenging §3(c)(2)(B), we do no more than set out the stipulation of the parties filed on August 25, 1980. That is, that §3(c)(2)(B) does not compel Mobay to enter into joint data development or cost sharing arrangements, and that §3(c)(2)(B)'s arbitration provisions are applicable only if Mobay first elects to enter into such arrangements. We find nothing to indicate that EPA's practices deviate from this. We therefore hold that the rest of Mobay's objections to §3(c)(2)(B) are without merit.

II

THE REGISTRATION PROCESS UNDER THE 1978 AMENDMENTS

A. *The FIFRA Regulations*

Mobay challenges the regulations which outline EPA's generic standards registration procedure. Mobay asserts that these regulations violate FIFRA, are arbitrary, capricious, and unlawful, and were promulgated without observance of procedure required by law.

The FIFRA registration regulations are published at 40 C.F.R. §§162.1 - 162.47 (1980). Those regulations, notably §§162.7(d), .8, .9-1 to 8, and .18-1 to 5, implementing FIFRA §§3(c)(1)(D), 3(c)(2)(D), and 3(c)(7) are the center of controversy.

Under the new registration scheme, EPA will conduct complete data evaluations for unconditional registrations under §3(c)(5) only when (1) reregistering currently registered products, (2) acting on applications for registration of products containing new chemicals, or (3) the EPA determines that it would otherwise serve the public interest. *Id.* §162.7(d)(1)-(2). All other applications will be considered as applications for conditional registration under §3(c)(7). *Id.* §162.7(e). *See id.* §162.18-1.

The applicant must submit a proper application supported with data that are available for review by EPA. *Id.* §162.18-3. Data are "available for review" if they are submitted by the applicant or are already in EPA's files, the applicant acknowledges reliance on them, and EPA may consider them in support of the application. *Id.* §162.18-2(a).

The applicant must make available for review data sufficient to allow EPA to determine that approval of the

application will not cause a significant increase in the risk of any unreasonable adverse effect on the environment. *Id.* §§162.8(a)(1), .18-2(c)(2), (d)(4). He also must submit any factual information regarding adverse effects which has been obtained by him or has come to his attention, and which he believes has not been submitted to EPA. *Id.* §162.8(a)(2), (b). Finally, he must also submit any additional data requested by EPA to support the application. *Id.* §162.8(a)(3), (c).

No application for registration will be granted unless the applicant complies with the compensation regulations found at §§162.9-2 to 8. *Id.* §162.9-1(a). The applicant shall include a generalized offer to pay compensation to all those persons whose data he relies upon. The wording of this general offer appears at §162.9-2,[22] and the EPA has published forms to be used in making these offers. See Plaintiff's Exh. Nos. 220-22.

If the EPA has published a generic standard for an active ingredient, data compensation is relatively simple. In addition to the generalized offer to pay compensation required by §162.9-2, an application need only include (1) a citation of each standard; (2) the registrable uses listed in the standard for which approval is sought; (3) an acknowledgment that the application relies on all data which, according to the standard, support the registrability of each such use; and (4) a statement that the applicant has notified each person listed as a submitter of such data

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22. Except as provided in §162.9-1(b), each application for any registration action shall include the following statement:

> [Name of applicant] hereby offers and agrees to pay compensation to other persons, with regard to the approval of this application, to the extent required by section 3(c)(1)(D) of the Federal Insecticide, Fungicide and Rodenticide Act, as amended, 7 U.S.C. sections 136a(c)(1)(D) and 136(c)(2)(D) [sic].

(which have been submitted after December 31, 1969), that he intends to rely on the other person's data to support his application, and has offered to pay compensation and commence negotiations to ascertain the terms and amount of compensation. 40 C.F.R. §162.9-3.[23]

Of course, virtually no generic standards have yet been published.[24] Consequently, applicants for the most

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23. §162.9-3 Data compensation in cases where a generic standard exists for an active ingredient.

Except as provided in §162.9-1(b), each application for any registration action concerning a product containing any active ingredient for which the Agency has published a final generic standard shall include:

(a) A citation of each such standard;

(b) The registrable uses listed in the standard(s) (or additional registrable uses, in the case of amendments) for which approval is sought;

(c) An acknowledgment that the application relies on all data which, according to the standard(s), support the registrability of each such use;

(d) A statement that the applicant has furnished to each person who, according to the cited standard(s), is an original submitter of an item of data submitted on or after January 1, 1970 which supports the registrability of applicant's product (other than persons with whom the applicant has agreed in writing on the amount and terms of payment of any compensation that may be payable under FIFRA section 3 with regard to approval of the application):

(1) A notification of the applicant's intent to apply for registration, including the proposed product name, a listing of the product's active ingredients, and the product's intended uses (or proposed additional uses, in the case of amendments);

(2) An offer to pay the person compensation, with regard to the approval of the application, to the extent required by FIFRA sections 3(c)(1)(D) and 3(c)(2)(D);

(3) An offer to commence negotiations to ascertain the amount and terms of compensation to be paid; and

(4) The applicant's name, address, and telephone number.

24. EPA had published at least one standard as of September, 1980, for the active ingredient Metolachlor. See Attachment A to Defendant's Post Trial Brief.

part must turn to §162.9-4.[25] In addition to the generalized offer to pay compensation, applicants must acknowledge that they rely on (1) all data which they have submitted or specifically cited, and (2) other data in EPA's files which concern (a) their product, (b) a similar or identical product, or (c) one or more active ingredients for which there is no generic standard, and which are the types of data EPA would require for a full scientific review under §3(c)(5) if it were issuing unconditional registrations.

This is known as the "cite all" method of support. Under this method, an applicant must rely on all data in EPA's files which are pertinent to an evaluation of his product, even if he has submitted his own data. Conceivably, then, he need submit no data at all, but only

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25. §162.9-4 Acknowledgment of reliance on data for products with active ingredients for which no generic standard exists.

Except as provided in §§162.9-1(b) and 162.9-8, each application for any registration action concerning a product containing any active ingredient for which EPA has not published a final generic standard shall include an acknowledgment that for purposes of FIFRA section 3(c)(1)(D) the application relies on (and any resulting registration should be regarded as if it were based on the Administrator's consideration of) the following data:

(a) All data submitted or specifically cited by the applicant in support of the registration; and

(b) Each other item of data in the Agency's files which:

(1) Concerns the properties or effects of:

(i) Applicant's product;

(ii) A product which is identical or substantially similar in composition to applicant's product; or

(iii) One or more of the active ingredients of applicant's product for which EPA has not yet published a final generic standard; and

(2) Is one of the types of data that EPA would require to be submitted for scientific review by EPA if the application sought the initial registration under FIFRA section 3(c)(5) of a product with composition and intended uses identical or substantially similar to those of the applicant's product, under the data requirements in effect on the date EPA approves applicant's present application.

"cite all" data in EPA's files and compensate the data submitters individually.[26] See Plaintiff's Exh. No. 220 (offer-to-pay statement for cite-all method of support).

"Cite all" is not the only method of support. EPA has provided an alternate procedure under §162.9-8[27] for ap-

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26. The procedure for paying compensation is set out at §162.9-5:

> §162.9-5 Offer of compensation in cases where §162.9-4 applies.
>
> Each application to which §162.9-4 applies shall also include a statement that the applicant has carefully examined the most recently published version of the EPA publication entitled "Pesticide Data Submitters by Chemical," and has furnished to each person listed as the original submitter of any data concerning any active ingredient of applicant's product for which EPA has not yet published a final generic standard (other than persons with whom the applicant has agreed in writing on the amount of any compensation that may be payable under FIFRA section 3 with regard to approval of the application):
>
> (a) A notification of the applicant's intent to apply for registration, including the proposed product name, a listing of the product's active ingredients, and the uses (or a summary of those uses) which will appear on the product's labeling if the application is approved (including previously-approved uses and proposed added uses);
>
> (b) An offer to pay the person compensation, with regard to the approval of application, to the extent required by FIFRA section 3(c)(1)(D) and section 3(c)(2)(D);
>
> (c) An offer to commence negotiations to ascertain which data is subject to the compensation requirement of FIFRA section 3(c)(1)(D) and the amount and terms of compensation, if any, to be paid; and
>
> (d) The applicant's name, address, and telephone number.

27. §162.9-8 Alternate procedure for certain applicants for conditional registration.

> (a) An applicant for conditional registration of a new product (or for conditional amendment of an existing registration) need not comply with §§162.9-4 and 162.9-5 if:
>
> (1) Each of the product's active ingredients is contained in some product currently registered under FIFRA;
>
> (2) The product will be labeled as an end-use product, as defined in §162.9-7(c); and

(Continued on following page)

plicants eligible for the formulator's exemption. An applicant may use the alternate method if

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Footnote continued—

(3) The applicant complies with paragraphs (b) through (f) of this section.

This section does not apply to other applicants.

(b) The applicant must furnish to EPA, with his application, a copy of each item of test data required to satisfy the minimum requirements for data that apply to the applicant's product and all of its uses, according to the Registration Guidelines (or instructions to the applicant by EPA), except that the applicant need furnish only data which are to be derived from tests using a formulated product as the test substance. All such data shall be derived from tests using the applicant's product (or another product with identical composition) as the substance tested.

(c) The applicant shall furnish with the data he submits a statement setting forth, to the best of his knowledge, the name and address of each person at whose expense each submitted item of data was generated, and how the applicant came into possession of each of the items of data (e.g., applicant generated the data; applicant obtained the data from another firm (identify); applicant copied data from a publication; applicant obtained a copy of the data from EPA).

(d) The applicant shall submit with his application a statement that EPA, in its evaluation of the properties, efficacy, and safety of the formulated end-use product, may not consider any data as supporting the application, except the following data:

(1) The data the applicant has submitted to EPA under paragraph (b) of this section;

(2) Other data pertaining to the safety of the product's active ingredients, rather than to the safety of the end-use product; and

(3) Existing tolerances, food additive regulations, exemptions, and other clearances issued under the Federal Food, Drug, and Cosmetic Act.

(e) If the applicant knows that any item of data he submitted under this section was generated by (or at the expense of) another person who originally submitted the data to EPA (or its predecessor, USDA) on or after January 1, 1970, to support an application for registration, experimental use permit, or amendment adding a new use to an existing registration, or for reregistration (unless the applicant and the original data submitter have reached

(Continued on following page)

1. He is registering his product as an "end-use" or formulated product.[28]

Footnote continued—

written agreement on the amount and the terms of payment of any compensation that may be payable under FIFRA section 3(c)(1)(D)(ii) with regard to approval of the application), the applicant shall submit to EPA a statement that he has furnished to each such identified original data submitter:

(1) A notification of the applicant's intent to apply for registration, including the proposed product name;

(2) An offer to pay the person compensation, with regard to the approval of the application, to the extent required by FIFRA sections 3(c)(1)(D) and 3(c)(2)(D);

(3) An identification of the item(s) of data to which the offer applies;

(4) An offer to commence negotiations to ascertain the amount and terms of compensation to be paid; and

(5) The applicant's name, address, and telephone number.

(f) If the applicant's product contains any active ingredient other than those that are present solely because of the incorporation into the product, during formulation, of one or more other registered pesticide products purchased from another producer, then the applicant shall also comply with §162.9-5 as to such active ingredient, and the application shall contain an acknowledgment that for purposes of FIFRA section 3(c)(1)(D) the application relies on (and any resulting registration should be regarded as if it were based on the Administrator's consideration of) the following data:

(1) All data submitted or specifically cited by the applicant in support of the registration; and

(2) Each other item of data in the Agency's files which:

(i) Concerns the properties or effects of any such active ingredient; and

(ii) Is one of the types of data that EPA would require to be submitted for scientific review by EPA if the applicant sought the initial registration under FIFRA Section 3(c)(5) of a product with composition and intended uses identical to those proposed for the applicant's product, under the data requirements in effect on the date EPA approves the applicant's present application.

28. An end-use product is the finished product, designed to be used as sold or after dilution by the user. It is to be distinguished from a "manufacturing-use product," which is a product designed to be used to manufacture an end-use product.

2. Each of his product's active ingredients is contained in a currently registered product.

3. He submits data derived from tests using either his own formulated product or another formulated product with identical composition. Data already in EPA's files concerning an identical end-use product may be cited instead of submitted.

4. Finally, EPA considers data pertaining to the safety of the product's active ingredients, rather than to the safety of the end-use product.[29] The alternate method user, being a formulator under §3(c)(2)(D), does not have to submit, cite, or compensate for the use of this safety data. See Plaintiff's Exh. No. 221 (offer-to-pay statement for alternate method of support).[30]

There is a third option available. If an applicant seeks to register a product containing any active ingredients derived from either an unregistered product or a registered product which is not purchased from another producer, he may use what is termed the "combined cite-all and alternate methods." Under the combined method, he simply (1) uses the alternate method and submits his own

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29. The EPA must also consider existing tolerances, food additive regulations, exemptions, and other clearances issued under the Federal Food, Drug, and Cosmetic Act. §162.9-8(d)(3).

30. Section 3(c)(2)(D) does not exempt a formulator from §3(c)(1)(D) to the extent that he relies on safety data not pertinent to the purchased product's safety. For example, to the extent he relies on data concerning the safety of similar end-use products. He must still offer to compensate those people. The "Pesticide Data Submitters by Chemical" list does not presently differentiate between types of data, however. The EPA thus recommends that applicants who believe they are eligible for the exemption nevertheless notify all companies identified on the list as having submitted data concerning a particular active ingredient. EPA says that negotiations should quickly disclose which data are exempt. *See* §162.9-7(d). The data submitters list, introduced at trial as Plaintiff's Exh. No. 252, does, as to many ingredients, differentiate between types of data.

end-use data or cites the end-use data of an identical end-use product, and (2) may submit or specifically cite other data, but he must "cite all" other data in EPA's files (except safety data pertinent to the purchased registered product, which the alternate method exempts him from relying on). See §162.9-8(f); Plaintiff's Exh. No. 222.[31]

If EPA determines that the product is not misbranded, that the labeling is correct, that the registrant has satisfied the data requirements and compensation regulations, and that the product will not significantly increase the risk of unreasonable adverse environmental effects, it shall issue a conditional registration. §162.18-4. The registration may be cancelled for failure to satisfy the conditions imposed by EPA. §162.18-5.

Mobay challenges the registration procedure as modified by the conditional registration and data compensation regulations. Its objections focus on (1) EPA's conditional-registration-only policy; (2) the "cite all" method; (3) EPA's interpretation of the formulator's exemption; and (4) the streamlining of the data requirements described by §162.8. Mobay also claims that EPA did not comply with the procedural requirements of FIFRA and the Administrative Procedure Act, 5 U.S.C. §553.

Mobay does not here challenge any of the 1978 amendments to FIFRA. Instead, it attacks EPA's interpretation and execution of those amendments, found in its regulations. We thus are called upon only to review action of a government agency.

In this context, we are empowered to

> decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the

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31. See note 29, *supra*.

meaning or applicability of the terms of an agency action. The reviewing court shall—

. . .

(2) hold unlawful and set aside agency action, findings, and conclusions found to be—

(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

. . .

(D) without observance of procedure required by law. . . .

5 U.S.C. §706 (1976). The two provisions of §706(2) are part of six, which are separate standards. *See Bowman Transportation, Inc. v. Arkansas-Best Freight Systems, Inc.*, 419 U.S. 281, 284 (1974).

1. *EPA's Conditional-Registration-Only Policy*

Mobay alleges that the EPA's practice of primarily issuing only conditional registrations under §3(c)(7)[32] violates FIFRA and is arbitrary, capricious, and unlawful.[33] Specifically, Mobay says that EPA is violating §§3(c)(3) and 3(c)(5) by failing to review the data it has submitted in support of its applications and, as expeditiously as possible, either granting it an unconditional

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32. EPA will conduct complete data evaluations for unconditional registrations under §3(c)(5) only:

(i) As part of the process of reregistering currently registered products;

(ii) When acting on applications for registration of products containing new chemicals; or

(iii) When the Agency determines that it would otherwise serve the public interest.

40 C.F.R. §162.7(d)(1).

33. The relevant regulations are 40 C.F.R. §§162.7(d)(1)-2, (e), .18-1 (1980).

registration under §3(c)(5), or denying its application. Mobay contends that §3(c)(7) was intended to operate as an additional, not an exclusive, registration authority.

The scope of our review of agency actions under 5 U.S.C. §706(2)(A) is narrow. *Baltimore and Ohio Chicago Terminal Railroad Co. v. United States*, 583 F.2d 678, 685 (3d Cir. 1978). We examine the FIFRA regulations only to determine whether they are "rationally supported." *Id.*

The legislative history of the 1978 amendments indicates that conditional registration was proposed as a means of eliminating the double standard which had resulted from applicants for registration failing to meet the stringent requirements of the 1972 amendments, while products registered before the amendments and subjected to a lesser standard of review remained on the market. For example, Congressman Fithian, sponsor of the House bill, stated:

> Most major manufacturers and pesticide formulators are experiencing difficulty in gaining approval for additional uses or changed uses of pesticides which were approved decades ago by the Government. The root of this problem is that the adequacy of the decades-old studies on which the approvals of current pesticides are based have been called into question. FDA and EPA have found sloppy practices—test results have been discovered that do not agree with underlying data—and have also concluded that risk assessments reached decades ago do not uniformly conform with the judgments scientists reach based on knowledge that has accumulated since then. As there are more than 1 million pieces of data in EPA's files, the dimensions of this problem are unknown, but the potential is disturbing.

> Thus EPA finds itself presently unable to take new registration actions where old chemicals are concerned without "validating" toxicity studies to reaffirm old findings or discover any problems and direct that new studies begin. It is preferable to conduct data validation systematically, taking the most important or widely used pesticides first. In fact, it appears that it would be virtually impossible to complete the task, or reach regulatory decisions based on the old studies in a reasonable period of time without a highly efficient program for data validation. In the interim, there is a need to provide a mechanism to modify current registrations to . . . accommodate new producers who wish to compete with identical products approved in the past. The conditional registration provisions of the bill are intended to meet the need to redress the inequitable double standard that will otherwise exist until data are validated during registration. The chemical giants and the small but vital formulators stand equally to gain from these provisions of H.R. 8681.

123 Cong. Rec. 36,007 (1977). The House Report echoes this:

> The provisions in H.R. 8681, as amended, providing for conditional registration are another important step in expediting the registration process. It is especially important to small companies who seek "me too" registrations to be able to produce pesticides already registered under a different name. FIFRA currently permits registered pesticides to remain registered until EPA takes cancellation action. Further, if EPA should require additional data, adequate time to develop the data must be granted during which time the pesticide can remain on the market. On the other

> hand, under present law a new registrant who wants to register and sell products exactly the same as those already registered cannot unless there is a complete validation of data and all necessary data are available. H.R. 8681 would tend to eliminate the inequity to small formulators in this situation.

H.R. Rep. No. 95-663, 95th Cong., 2d Sess. 19, *reprinted in* [1978] U.S. Code Cong. & Ad. News 1966, 1992. *See also* S. Rep. No. 95-334, 95th Cong., 1st Sess. 10 (1977).

We understand EPA's practice of issuing conditional registrations to be a response to the dilemma that it and applicants found themselves in. EPA was faced with the impracticability of conducting full data reviews for the unconditional registration of numerous products, and with the inequitable circumstance of denying pesticides access to a market which before 1972 they could have reached. Conditional registration permits these products to reap the commercial fruits enjoyed by products registered under a lesser standard. All that need be shown is that allowing the pesticides on the market will not significantly increase the risk of unreasonable adverse effects on the environment already existing.

Mobay apparently views conditional registrations as tenuous privileges, having less permanence than an unconditional registration. It fears that it will forever be required to supply EPA with additional data, upon pain of cancellation for noncompliance with a condition. But this ignores the existence of §3(c)(2)(B), which subjects even unconditional registrants to requests for additional data.

Conditional registration also operates as a stopgap mechanism for registering pesticides while EPA changes from its registration program based on reviewing individual applications, to its generic standards registration pro-

gram. By establishing conditions and using its §3(c)(2)(B) authority, the EPA can receive data from both conditional and unconditional registrants to aid in compiling each generic standard.

In sum, we do not believe that EPA's conditional-registration-only policy violates FIFRA §§3(c)(3) and 3(c)(5). Section 3(c)(7) explicitly states, "Notwithstanding the provisions of subsection (c)(5)," the Administrator may issue conditional registrations or amendments. Thus, §3(c)(3) must now be read as compelling EPA to either unconditionally register a pesticide under §3(c)(5), or conditionally register a product under §3(c)(7), "as expeditiously as possible."

Next, we consider Mobay's challenges to the revision of §162.8. Until it was revised, §162.8 had described the types of data necessary for supporting applications. See 40 C.F.R. §162.8 (1978). (The data requirements described in §162.8 are not to be confused with the data guidelines which EPA must publish pursuant to §3(c)(2)(A). The purpose of the guidelines is to specify the kinds of information which will be required to support registration. 40 Fed. Reg. 28,242, 28,248 (1975). Section 162.8 does not preempt the guidelines, but delineates the major data requirements of the guidelines, and directs the applicant to them. *Id.*) For example, under §162.8(b), an applicant for new registration was told to submit efficacy, general and environmental chemistry, and hazard data. These requirements were described only in a general way, but they were helpful in indicating the types of tests which an applicant should perform with his product. It is the deletion of §162.8(b) which Mobay in particular challenges.

Section 162.8 was significantly revised in 1979. Now, an applicant for conditional registration is informed that

he must (1) furnish or refer to data adequate to demonstrate that his pesticide will not significantly increase the risk of adverse environmental effects,[34] (2) submit any factual information regarding adverse effects of the pesticide on the environment, and (3) submit additional data as they are requested by EPA. In other words, he need not furnish the complete data base described by former §162.8.

Mobay says that it is now impossible for it to know with certainty what data it must submit, since §162.8's requirements are indefinite, and there are no published data guidelines under §3(c)(2)(A), other than those EPA has issued in proposed form.

It is apparent that §162.8 was revised to conform the data requirements to EPA's practice of issuing conditional registrations. By requiring the submission of a complete data base, former §162.8 had been fostering the double standard which §3(c)(7) is now rectifying.

The revision of §162.8, then, has really changed nothing insofar as data requirements are concerned. The guidelines are being issued, albeit gradually, in proposed form, and EPA has indicated they will serve as a general statement of policy. 43 Fed. Reg. 29,696 (1978).

2. *The "Cite All" Method of Support*

Mobay challenges the compensation regulations, particularly the "cite all" method of supporting applications with data. Mobay contends that the compensation regulations violate FIFRA and are arbitrary, capricious, and unlawful. It says that §3(c)(1)(D) explicitly gives an

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34. An applicant for unconditional registration must furnish or refer to data adequate to demonstrate that the product will not cause unreasonable adverse effects on the environment.

applicant three methods of support it may follow. It may (1) submit its own data, or, alternatively (2) cite data that appears in the public literature that EPA may consider in accordance with §3(c)(1)(D)'s compensation provisions, or (3) cite data that previously had been submitted to EPA and the EPA may consider in accordance with §3(c)(1)(D)'s compensation provisions. Mobay believes that its own data is more than adequate to support its applications, and that it should not have to rely on someone else's data which Mobay has not even seen.

EPA addressed this argument in the prologue to the compensation regulations:

> The commenters argue that this language means that an applicant has the option of submitting all required data himself or instead relying on previously-submitted data.
>
> These comments appear to be premised on the idea that if the Agency has specified (in data guidelines or elsewhere) the *minimum* number of tests for various toxic effects that must be conducted, and the applicant has furnished test reports complying with those minimums, and showing no unreasonable adverse effect, then the Agency should unconditionally register the product based *solely* on the data submitted, even though other pertinent data are available. What this premise overlooks is that the Agency, for good reason, is unwilling to confine its section 3(c)(5) review to what the applicant presents if, in fact, a broader range of data exist. In toxicity testing, for instance, the issue often is not merely whether a pesticide causes a particular toxic effect or how toxic the pesticide is, but also *how certain* we are of the validity of a set of findings. If a second test of a pesticide for some toxic effect produces results which corroborate

the findings of an earlier test, each set of test results gains credibility from the other. On the other hand, if the second test results are significantly different (as is not uncommon in some kinds of toxicity testing), careful review is required to attempt to explain the differences and to decide what the Agency's position should be. Thus, the more data of a given type there are for comparison, the more confident the Agency can be that its regulatory decision is sound.

Moreover, the quoted portion of section 3(c)(1)(D) does not direct the Agency to grant a section 3(c)(5) registration based on consideration of less than all the available pertinent data, nor do we believe Congress would desire this. We read the language in question, rather, as a Congressional recognition that in some cases (e.g., application for registration of products containing newly discovered active ingredients) the *only* available data are those which the discoverer submits with his application, and that in such a case the applicant must submit "a *full* description of the tests made and the results thereof upon which the claims are based" (emphasis added). This phrase appeared in the 1947 FIFRA, and was retained in the 1972 FIFRA amendments. A 1972 Report of Senate Committee on Agriculture and Forestry said, in rejecting a proposed amendment to this language:

The major purpose of the act is to protect the public from pesticides which are not efficacious or which endanger health or the environment. The Administrator should be able to request and obtain a full description of the tests upon which claims for the pesticide are based. He should not be restricted to such tests as the applicant may choose to offer. There should be no question about this. The Administrator

must make a decision, which is subject to judicial review, on the basis of the information available to him. For the protection of the public and as a simple matter of reasonable administration, all relevant information should be available to him.

S. Rep. No. 92-838, 92d Cong., 2d Sess., Supplement p. 34 (October 3, 1972).

It would be ironic indeed if this same "full description" language were to be transformed into a justification for obtaining unconditional registration on the basis of some *portion* of the available data chosen by the applicant.

44 Fed. Reg. 27,945, 27,946-47 (1979).

We believe this rationale is persuasive, and is supported by a closer reading of §3(c)(1)(D). Under that section, an applicant must, *if requested by the Administrator*, either submit its own data or cite other data. Section 3(c)(1)(D) gives EPA a selection of three methods for supporting applications, and EPA, by its "cite all" regulations, can be said to have "requested" that applicants use all three.

With its alternate method under §162.9-8, on the other hand, EPA has determined that an applicant need not cite end-use (formulation) data, but may submit that which he himself has generated. EPA permits this because a large number of persons have submitted end-use data on any given product, and it would be unduly expensive and burdensome for an applicant to have to compensate all the data submitters under "cite all." 44 Fed. Reg. at 27,947-48.

We also believe that the "cite all" method is consistent with the philosophy of the developing generic stan-

dards program. By relying on a generic standard to support its application, an applicant will, in effect, be "citing all" data.

Mobay's compensation rights are protected under "cite all." Data submitters are grouped by active ingredient either in the generic standard or on the list of "Pesticide Data Submitters by Chemical" (See Plaintiff's Exh. No. 252). In the event that an applicant fails to offer compensation to Mobay for relying on its data, or for some reason Mobay is not included as a data submitter for an active ingredient on the data submitters list, it may discover whether any of its data was used by reading the registration statement issued by EPA 30 days after a pesticide is registered. *See* §3(c)(2)(A), 7 U.S.C.A. §136a(c)(2)(A).

Mobay also challenges EPA's interpretation of the formulator's exemption under §3(c)(2)(D), as expressed in §162.9-7.[35] Section 3(c)(2)(D) provides:

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35. §162.9-7 Exemption.

(a) Under FIFRA section 3(c)(2)(D), an applicant who seeks registration, reregistration, or amended registration of an end-use product (as defined in paragraph (c) of this section) is exempt from the compensation requirement imposed by FIFRA section 3(c)(1)(D) with respect to data which pertain to the safety of any other registered pesticide product which the applicant purchases from another producer and uses in formulating his product.

(b) Data pertain to the safety of a purchased product if they would be scientifically pertinent to an Agency evaluation of the safety of the purchased product or one or more of its ingredients, rather than pertinent merely to an evaluation of the safety of an end-use product. To be pertinent to the purchased product's safety, the data need not have come from a test using the particular producer's product. For instance, any toxicity data from a test in which a reagent-grade, laboratory-grade, or technical-grade active ingredient was the substance tested normally would be scientifically pertinent to an evaluation of the safety of any pesticide product containing that active ingredient (with certain exceptions depending on use patterns). However, toxicity data from a test in which the substance tested was a

(Continued on following page)

(D) Exemption.—No applicant for registration of a pesticide who proposes to purchase a registered pesticide from another producer in order to formulate such purchased pesticide into an end-use product shall be required to—

(i) submit or cite data pertaining to the safety of such purchased product; or

(ii) offer to pay reasonable compensation otherwise required by paragraph (1)(D) of this subsection for the use of any such data.

7 U.S.C.A. §136a(c)(2)(D). The formulator's exemption is one facet of the generic standards program.

Footnote continued—

formulated, end-use product (whether or not use-diluted) normally would pertain only to the safety of the same end-use product, closely similar end-use products, or their ingredients, but not to the safety of other end-use products.

(c) As used in this section, the term "end-use product" means a pesticide product whose labeling bears instructions for using or applying the product (as packaged and sold, or after dilution by the applicator) for controlling pests or regulating plant growth. The term excludes products whose labeling allows use of the product to formulate other pesticide products.

(d) FIFRA section 3(c)(2)(D) does not provide an exemption from the FIFRA section 3(c)(1)(D) compensation requirements to the extent that an application relies on efficacy data, or on safety data not pertinent to the purchased product's safety (e.g., data concerning the safety of similar end-use products). FIFRA sec. 3(c)(1)(D) requires the applicant to furnish a compensation offer to the original submitters of such data. The "Listing of Pesticide Data Submitters" (see §162.9-5) does not at this time differentiate between types of data submitted. Accordingly, applicants for registration actions on end-use products should comply with the requirements in §162.9-5 (furnish compensation offers to all listed data submitters with whom no written agreement has been reached), to avoid the risk of summary cancellation or denial as provided in FIFRA section 3(c)(1)(D)(ii). Negotiations with listed data submitters should quickly disclose which data are exempt from the compensation requirement.

EPA interprets §3(c)(2)(D) as stating that

> an applicant who seeks registration, reregistration, or amended registration of an end-use product . . . is exempt from the compensation requirement imposed by FIFRA section 3(c)(1)(D) with respect to data which pertain to the safety of any other registered pesticide product which the applicant purchases from another producer and uses in formulating his product.

40 C.F.R. §162.9-7(a). Under EPA's interpretation, if two firms have submitted data pertaining to the safety of a registered manufacturing-use product containing a certain active ingredient, and a formulator purchases the registered manufacturing-use product from one company and formulates it into an end-use product, the formulator is exempted from citing, and compensating for reliance on, both companies' safety data.

Mobay, however, reads §3(c)(2)(D) as exempting the formulator from paying compensation only to the person from whom it purchased the manufacturing-use product. All other data submitters, Mobay asserts, must still be compensated.

The rationale for EPA's construction is found in the statement made by Douglas Costle, Administrator of EPA, at hearings held before a House subcommittee:

> As we testified last month, it has become increasingly clear that we are spending far too much time on individual end-use formulation applications, and that the whole structure for registration needs to be focused primarily on the chemicals themselves rather than thousands of individual applications for products containing mixtures of chemicals. Section 1 of our bill would facilitate that restructuring. We envision

a system in which it is the technical material which becomes the focal point for registration, with the bulk of the safety data obtained from manufacturing-use, rather than end-use, registrations. This would mean that the issues of compensation for the most expensive data—chronic feeding, environmental chemistry, fish and wildlife, and so forth—would be worked out among the registrants of technical products. The cost of that data could be included in the price for which the technical product sells. Thus, the formulator would in effect be buying data rights along with the technical material, without having to go through the 3(c)(1)(D) procedures. Formulators might have to engage in 3(c)(1)(D) transactions for data specifically pertaining to the end-use formulation—if that data had been submitted by another formulator, for instance—but such transactions would be relatively simple. In other words, we see two sets of registrants who must settle up with one another: registrants of technical or manufacturing-use materials, and registrants of formulated products. We believe that the Act should specifically advocate this dichotomy, and specify that formulators who purchase a registered pesticide product from another producer need not submit data pertaining to the safety of the purchased product, as opposed to the safety of the formulated end-use product. EPA could then proceed to call-in technical products for reregistration first, as the initial step toward making the transition from an end-use to a generic approach to the registration process.

Extending and Amending FIFRA: Hearings Before the Subcomm. on Department Investigations, Oversight, and Research of the House Comm. on Agriculture, 95th Cong., 1st Sess. 154-55.

The report accompanying the Senate bill, which contained a provision virtually identical to §3(c)(2)(D), stated:

> The Subcommittee agreed to the provision in S. 1678 authorizing the Administrator to make one safety finding on a basic ingredient that would apply to all pesticides using that ingredient.
>
> It was noted that once the Administrator made a finding that there were no unreasonable adverse effects to the environment caused by a basic ingredient, or "generic" chemical, it would be a waste of resources to review that decision each time an application was received for the registration of an end-use product containing the generic chemical and supported by the data base used to establish the original registration.
>
> Under the provision adopted by the Subcommittee, the formulator of an end-use product who uses a registered technical material would only furnish or cite data pertinent to the end-use and not have to cite data supporting the technical registration.

S. Rep. No. 95-334, 95th Cong., 1st Sess. 8-9 (1977). The conference committee adopted the Senate bill, with a modification.

EPA insists that its interpretation must control in order to prevent data submitters from receiving what it terms a double recovery of compensation. EPA says that when the seller registered his manufacturing-use product, he paid compensation to the data submitters. It would be incongruous to require a formulator to pay both the manufacturing-use producer and the data submitters whose data supported the manufacturing-use registration, EPA says, since they were already compensated once. EPA suggests that the seller of the manufacturing-use product

may include in the selling price a percentage of the compensation he paid these data submitters.

If the manufacturing-use registrant generated the data himself, EPA says that he may include this cost in the selling price, too.

In view of the evidence in the legislative history of EPA's desire to streamline the registration process and to avoid situations where data submitters receive double recovery, and upon a reading of §3(c)(2)(D) itself, we find that §162.9-7 is consistent with that section.

We do not believe that §162.9-7 denies Mobay due process, deprives it of its property without just compensation and for a private purpose, or denies it equal protection of the law. With regard to the due process violation and taking claims, our justification is the same as that given in our analysis of §3(c)(1)(D). As to the equal protection claim, we do not believe Congress' and EPA's treatment of submitters of safety data supporting the registration of manufacturing-use products is irrational. *Vance v. Bradley*, *supra*, 440 U.S. at 97.

We have studied the compensation regulations and the three methods of support they describe; that is, "cite all" (§162.9-4 to 5), alternate (§162.9-8(a)-(e), and combined (§162.9-8(f)) methods, and find them to be consistent with §§3(c)(1)(D) and 3(c)(2)(D).[36] Pursuant

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36. The offer-to-pay statement for the alternate method states that it is to be used "in connection with an application for registration of an end-use product which contains active ingredients, all of which are derived from registered and purchased products" under §162.9-8. It is not obvious, however, from reading §162.9-8 that the alternate method is available only to applicants who purchase registered products and formulate them into end-use products under §3(c)(2)(D). Section 162.9-8(a)(1) requires only that "[e]ach of the product's active ingredients is contained in some product currently registered under FIFRA."

(Continued on following page)

to authority given it by §3(c)(1)(D), EPA has established a system of data submission and data citation designed to provide itself with as complete a data base as possible, increase competition in the pesticide industry and minimize the regulatory burden on applicants.

Therefore, we hold that the conditional registration regulations and the compensation regulations are not arbitrary, capricious, or unlawful within the meaning of 5 U.S.C. §706(2)(A).

B. *Promulgation of the Regulations*

Though we find the regulations to be valid substantively, we must also determine that they were promulgated properly. 5 U.S.C. §706(2)(D). Mobay contends that they were promulgated in violation of FIFRA and the Administrative Procedure Act, 5 U.S.C. §553.

A proposed rule concerning data compensation under §3(c)(1)(D) was published June 20, 1977, at 42 Fed. Reg. 31,284. This was more than a year before the 1978 amendments were enacted. Hence, it did not, and could not, reflect such features as "cite all," the generic registration standards program, and the formulator's exemption.

EPA was aware of this. It stated in its explanation of the proposed rule that

> Congressional hearings on the amended FIFRA are pending. Among the matters which are being

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Footnote continued—

That §162.9-8(a)(1) might describe registered *purchased* products is deducible from reading subsection (f), which operates when "the applicant's product contains any active ingredient other than those that are present solely because of the incorporation into the product, during formulation, of one or more other registered pesticide products purchased from another producer."

considered is substantive amendment to section 3(c)(1)(D) of the Act. Any legislative amendment will, of course, be reflected in the regulations before they are published in final form. If a major legislative amendment requires it, these regulations will be re-proposed for public comment.

Id.

As for the conditional registration regulations, notice of them was provided by an advance notice of proposed rulemaking published July 25, 1978, at 43 Fed. Reg. 32,154, two months before §3(c)(7) was enacted. EPA stated that it was preparing the regulations nevertheless, with promulgation contingent upon enactment. *Id.* at 32,154-55. The notice described conditional registration as being a registration "contingent upon the later submission of certain data normally required prior to registration." *Id.* at 32,155. It said further:

> The regulations will specifically discuss the applicable definitions, the data and other requirements, and procedures and conditions under which conditional registrations of each type will be granted. In addition, procedures for the denial and cancellation of conditional registrations will be addressed.
>
> Related issues which will impact on the regulations, and which commenters may wish to address include (1) compensation for and exclusive use of data; (2) the so-called "horizontal line," whereby registrants of formulated products need not submit safety data on the purchased manufacturing use product; (3) the Agency's intent to use proposed re tion guidelines on chemistry, toxicology, and environmental safety as the determinant of data requirements for compensation purposes; and (4) the use of the EPA

> Data Catalog as the prime reference source for both applicants and the Agency for citation of available data to meet the requirements.

Id. EPA also noted that part of the regulations would be published as interim final regulations, and become effective immediately upon promulgation, subject to revision based on comments received after publication. *Id.*

The 1978 amendments were enacted on September 30, 1978. On October 6, 1978, EPA circulated a working draft of the conditional registration and compensation regulations to "over 2,500 interested industry, environmental and consumer groups, state and local agencies, and agricultural organizations." 44 Fed. Reg. at 27,933, 27,950. On October 10, 1978, EPA published a notice of an open public meeting to be held November 6, 7, and 8, at EPA's offices in Washington. 43 Fed. Reg. 46,555 (1978). The purpose of the meeting was to solicit comments and information concerning the proposed regulations.

This meeting was held. On May 11, 1979, both sets of regulations were published in final and interim final form at 44 Fed. Reg. 27,932 and 27,945. Both were effective immediately, with comments on the conditional registration regulations being accepted until July 10, 1979.

EPA acknowledged that the compensation regulations differed significantly from those proposed in June of 1977. But it believed that

> reproposal under 5 U.S.C. 553(b) would be contrary to the public interest because of the long delay that reproposal would cause in the ability of persons to obtain pesticide registrations or to know the bases upon which registration will be granted. The need to quickly remedy statutory and administrative difficulties which

> have nearly halted pesticide registration activity was a major reason for passage of the EPA [*sic*], as the legislative history of the EPA [*sic*] clearly shows.

Id. at 27,950. It believed that the circulation of the working draft of the regulations and the public meeting held in November had provided sufficient notice of and opportunity to comment upon the proposed regulations. *Id.* at 27,950-51. The agency said it would conduct a review in late 1979 to decide whether revisions were needed. *Id.* at 27,951. EPA also relied on this rationale to find good cause for making the compensation regulations effective upon publication rather than 30 days later, as required by 5 U.S.C. §553(d). *Id.*

As justification for its promulgation of the conditional registration regulations, the agency relied upon the fact that it had published its advance notice of proposed rulemaking, inviting comments concerning the subject of conditional registration, circulated the working draft, and held the three-day public meeting. Insofar as making the regulations effective immediately, EPA said:

> The Administrator has determined that there are compelling public interest reasons for this regulation to be published as an interim final regulation at this time.
>
> Because this conditional registration regulation permits the Agency to eliminate the double standard for registration and resume the registration program as quickly as possible, the Administrator believes that the public interest is best served by making this regulation effective upon publication.

Id. at 27,933.

Under §25(a) of FIFRA, 7 U.S.C.A. §136w, the Administrator of EPA is authorized to prescribe regulations to carry out the provisions of FIFRA. At least 30 days before signing any regulation in final form for publication in the Federal Register, he shall provide the Secretary of Agriculture with a copy of the regulation, and simultaneously publish this notification in the Federal Register. The Administrator did this as to both sets of regulations. *See* 44 Fed. Reg. 18,225 (1979) (conditional registration regulations) and *id.* (compensation regulations). He also must furnish a copy to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture and Forestry of the Senate. This was done. *Id.* Finally, the regulation must be submitted to the FIFRA scientific advisory panel established by §25(d), 7 U.S.C.A. §136w(d). This, too, was done. *Id.* and *id.* at 18,225-26.

We find that the compensation and conditional registration regulations were promulgated in compliance with procedures required by FIFRA.

Next, we must determine if the agency complied with the rule-making procedures of the Administrative Procedure Act, described in 5 U.S.C. §553. In pertinent part, they require that

> (b) General notice of proposed rule making shall be published in the Federal Register, unless persons subject thereto are named and either personally served or otherwise have actual notice thereof in accordance with law. The notice shall include—
>
> (1) a statement of the time, place, and nature of public rule making proceedings;
>
> (2) reference to the legal authority under which the rule is proposed; and

(3) either the terms or substance of the proposed rule or a description of the subjects and issues involved.

Except when notice or hearing is required by statute, this subsection does not apply—

(A) to interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice; or

(B) when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.

(c) After notice required by this section, the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation. After consideration of the relevant matter presented, the agency shall incorporate in the rules adopted a concise general statement of their basis and purpose. . . .

(d) The required publication or service of a substantive rule shall be made not less than 30 days before its effective date, except—

(1) a substantive rule which grants or recognizes an exemption or relieves a restriction;

(2) interpretative rules and statements of policy; or

(3) as otherwise provided by the agency for good cause found and published with the rule.

We consider first the compensation regulations. The publication of the proposed rules on June 20, 1977 was insufficient notice of the final regulations, as it occurred more than one year before §3(c)(1)(D) was significantly changed. After all, EPA itself assured that the regulations would reflect any legislative amendment before being published in final form, and that they would be reproposed if a major legislative amendment required it.

Arguably, the advance notice of proposed rulemaking published in July of 1978, provided adequate notice of the compensation regulations, since it requested comments on certain general compensation issues. *See* 43 Fed. Reg. 32,154, 32,155. But this failed to give "either the terms or substance of the proposed rule or a description of the subjects and issues involved" within the meaning of §553(b)(3), which we believe comprehends concrete proposals parties may address, and not "amorphous subject areas." *See National Tour Brokers Association v. United States*, 591 F.2d 896, 901 (D.C. Cir. 1978).

The circulation of the working drafts to over 2500 groups was intended to be a substitute for the notice-and-comment procedure. The drafts were sent out on October 6, 1978, and EPA allowed a three week period for the submission of comments concerning them. A review of the administrative record, Defendant's Exh. No. 1, reveals that many pesticide companies received copies of the drafts too late to allow sufficient time to review them and submit comments, although other companies did submit comments.

The requirements of the notice-and-comment procedure of §553(b) may be excused, "when the agency for good cause finds . . . that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest." 5 U.S.C. §553(b)(B).

EPA does not suggest that providing sufficient notice and comment was unnecessary, nor does it show how it would have been impracticable to do so.

As to the allowance of time for notice and comment being contrary to the public interest, EPA urges that reproposal would have delayed the ability of applicants to obtain registrations or know the bases upon which registrations would be granted.

While we by no means wish to be understood as condoning or recommending EPA's disregard of the notice-and-comment procedure, we believe that the "public interest" exception should operate here. There is an urgent need for pesticides. The registration process has been slowed and tainted with uncertainty since this action was filed two years ago. By now, applicants should be familiar with the changes wrought by the 1978 amendments to FIFRA and by the new regulations. We believe that it is important to resume the registration process as quickly as possible. We repeat, however, that our sanctioning of EPA's attempts at providing notice and comment does not constitute approval, and is limited solely to this one situation.

As to the conditional registration regulations, we find that the public was given sufficient notice and opportunity to comment upon them. The advance notice of proposed rulemaking provided what we believe was a "description of the subjects and issues involved."

EPA, as mentioned above, made both the conditional registration and compensation regulations effective immediately because of the importance of resuming registrations as quickly as possible. In other words, EPA says it acted in the public interest, and this constitutes good cause for noncompliance with the 30-day publication rule of 5 U.S.C.

§553(d). For the same reasons given in regard to the notice-and-comment procedures, we believe that there was good cause for making both sets of regulations effective immediately.

III

DELETION OF DEADLINE FOR REREGISTRATION

In *Mobay Chemical Corp. v. Costle*, 447 F. Supp. 811 (W.D. Mo. 1978), the district court, Judge Hunter presiding, found that 23 registrations relying on Mobay's data without its permission and offers of compensation had been issued in violation of §3(c)(1)(D) of the 1972 amendments. The court did not cancel those registrations, however. Instead, the court observed that Mobay would receive its compensation when EPA reregistered the 23 products. *Id.* at 823-24.

At the time that case was decided, the deadline for reregistration was October 21, 1977. Congress changed this deadline by the 1978 amendments, however, after the case was decided. Now, under §3(g), 7 U.S.C.A. §136a(g), the Administrator is to reregister pesticides "in the most expeditious manner practicable." As we mentioned earlier, EPA says reregistration may not be completed for 10 to 15 years.

Mobay alleges, in Count III, that §3(g) constitutes a taking of its property without due process or just compensation, in that it deprives Mobay of compensation rights established by a judgment. Mobay seeks a declaratory judgment to that effect. Mobay also asks us to order that EPA immediately reregister the 23 products so that it may obtain the compensation due it. Alternatively, Mobay asks that we order EPA to cancel the registrations of the 23 products.

Section 3(g) does not repeal the reregistration provisions of FIFRA, but instead sets an affirmative, albeit indefinite, timetable for reregistration. Mobay's right to compensation has not been abrogated.

Delay in the payment of just compensation to a property owner whose property has been taken may violate the fifth amendment. *See, e.g., Joslin Manufacturing Co. v. City of Providence*, 262 U.S. 668, 677 (1923). But we have found above that it is not the purpose of §3(c)(1)(D) to provide just compensation from the government to data submitters whose data is used to support other applicants' registrations. Rather, §3(c)(1)(D) facilitates payment of compensation between private parties. *Chevron Chemical Co. v. Costle*, 499 F. Supp. 732, 742-43 (D. Del. 1980).

Of course, Mobay does have a vested right in the judgment it obtained in the Missouri litigation. Arguably, this gives it a property interest which may be the subject of a taking. We do not determine whether §3(g) effects a taking of Mobay's property, however, because we find that §3(g) has not withdrawn its Tucker Act remedy. *Regional Rail Reorganization Act Cases, supra*, 419 U.S. at 126. Having found that Mobay has recourse to the Court of Claims under the Tucker Act, litigation of whether §3(g) constitutes a taking must take place there. *Duke Power Co. v. Carolina Environmental Study Group, Inc.*, 438 U.S. 59, 94 n.39 (1978). *Accord, Chevron Chemical Co. v. Costle, supra*, 499 F. Supp. at 737, 743.

We next consider Mobay's request for an order directing EPA either to reregister the 23 products immediately, or else cancel their registrations. In the memorandum accompanying our order of July 15, 1980, denying EPA's motion for summary judgment, we expressed our reservations whether we had jurisdiction to do this, since Judge

Hunter had expressly decided not to make these orders. Since the time of that memorandum, however, the Missouri litigation has been transferred to this district, by order of Judge Hunter, dated February 26, 1981, and we now have jurisdiction to adjudicate Mobay's request for injunctive relief.

Judge Hunter justified his decision not to cancel the registrations of the 23 products by quoting from the legislative history of the 1975 FIFRA amendments:

> *It is not the intent of the conferees that existing registrations are to be invalidated because the conference committee has determined that data submitted after January 1, 1970, is compensable and that the data compensation provision applies to all applications for registration and reregistration submitted after October 21, 1972. Rather, the reregistration process is about to commence and it is expected that data compensation under Section 3(c)(1)(D) will be provided, where appropriate, during the reregistration process.* Cong. Record, S. 20460, Nov. 19, 1975 (remarks of Senator Allen). [Emphasis supplied.]

While the legislative history thus expresses a Congressional desire to expedite the registration process by clarifying the provisions of §3(c)(1)(D), it also clearly recognizes the need to permit registrations granted without regard to the compensation provisions of §3(c)(1)(D) to exist pending the application of the statutory provisions upon reregistration of those products. Given the legitimate confusion which has surrounded the application of this statute, any other resolution would be manifestly unfair and unnecessary.

> Applying the compensation provisions of §3(c)(1)(D) upon reregistration of those products previously registered guarantees that plaintiff will receive compensation in connection with those products for which compensation is warranted without invalidating existing registrations and creating administrative havoc. Thus, although the registrations of which plaintiff complains were in fact granted in violation of the compensation provisions of §3(c)(1)(D), Congressional recognition of the legitimate confusion concerning those provisions resulted in a clear expression of Congressional desire not to invalidate those improperly-granted registrations. See also S.Rep.No. 94-452, 94th Cong., 1st Sess., Nov. 10, 1975, U.S. Code Cong. & Admin. News 1975, p. 1359. In short, plaintiff will receive any relief to which it is entitled not immediately, but upon reregistration of the products registered under FIFRA of 1947.

Mobay Chemical Corp. v. Costle, *supra*, 447 F. Supp. at 823-24.

We note that Judge Hunter issued his decision in March of 1978, after the October 21, 1977 deadline set for reregistration had passed. He thus could not have assumed that there was any deadline for reregistration, or that Mobay would soon be receiving compensation.

We believe that the legislative history relied on by Judge Hunter is still persuasive. Mobay is definitely entitled to compensation under §3(c)(1)(D), and it will receive it upon reregistration. Congress has exhorted EPA to perform reregistration in the most expeditious manner practicable. In view of the thousands of products which must be reregistered on a priority basis, from the most dan-

gerous down to the least, we decline to interfere with the reregistration process.

We also decline to order EPA to cancel the 23 registrations. Since the 23 registrants are not present before us, or a part of this proceeding, we hesitate to issue such summary relief.

Consequently, we deny Mobay's request for declaratory and injunctive relief under Count III.

An order follows.

/s/ Barron P. McCune
Barron P. McCune
United States District Judge

Dated: June 12, 1981.

cc: Counsel of record.

IN THE
UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT
OF PENNSYLVANIA

Civil Action No. 79-591

MOBAY CHEMICAL CORPORATION,
Plaintiff,
vs.
DOUGLAS M. COSTLE, Administrator, U.S.
Environmental Protection Agency,
Defendant.

ORDER

AND NOW, June 12, 1981, for the reasons stated in the foregoing memorandum, the relief sought by the plaintiff is denied in all respects and judgment is entered for defendant. Each party shall bear his own costs.

/s/ Barron P. McCune
Barron P. McCune
United States District Judge

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IN THE
UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT
OF PENNSYLVANIA

Civil Action No. 81-373

MOBAY CHEMICAL CORPORATION,
Plaintiff,

vs.

DOUGLAS M. COSTLE, Administrator, U.S.
Environmental Protection Agency,
Defendant.

MEMORANDUM

BARRON P. McCUNE, District Judge
Dated: June 12, 1981.

We consider defendant EPA's Motion to Vacate and Dissolve Injunction issued by Judge Elmo B. Hunter of the United States District Court for the Western District of Missouri.

Judge Hunter granted declaratory and injunctive relief to plaintiff, Mobay Chemical Corporation (Mobay), from the operation of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C.A. §§136-136y (1980) in certain respects. He issued his order on March 14, 1978. *See Mobay Chemical Corp. v. Costle*, 447 F. Supp. 811, 834-35 (W.D. Mo. 1978). On September 30, 1978, FIFRA was amended. Many of the amendments altered provisions of FIFRA which had been the subject of Judge Hunter's order.

On June 29, 1979, defendant filed the instant motion pursuant to Fed. R. Civ. P. 60(b). It asserted that the

amendments now authorized what the injunction prohibited. It contends that it is unnecessary and inequitable for the injunction to operate in the face of the 1978 amendments.

Earlier, on May 1, 1979, Mobay had filed a complaint in this district at Civil Action No. 79-591, challenging the 1978 amendments. By memorandum and order filed concurrently with this memorandum and order, we have adjudicated that case.

By order filed February 26, 1981, Judge Hunter transferred the defendant's Motion to Vacate and Dissolve to this court.

Judge Hunter's 1978 order contains 14 paragraphs, 5 of which defendant seeks to have deleted or modified.

In Paragraph No. 9, Judge Hunter

> ORDERED that defendant, his officers, agents, employees and representatives be, and they are hereby, forever and permanently enjoined from considering or using any information, research and test data submitted by plaintiff to the Administering Agencies on or after January 1, 1970, which contains or relates to trade secrets or other confidential or privileged commercial or financial information in support of any application for registration in which an applicant seeks to rely on such data until such time as defendant shall have obtained the express written permission of plaintiff.

Section 3(c)(1)(D), as amended in 1978, permits EPA to use data submitted on or after January 1, 1970, by an applicant to support other applications without the permission of the data submitter, unless the data submitter is eligible for the exclusive use provision found in §3(c)(1)(D)(i), 7 U.S.C.A. §136a(c)(1)(D)(i). We have today found

§3(c)(1)(D) to be valid. Consequently, we delete Paragraph No. 9 from Judge Hunter's order.

In Paragraph No. 3, Judge Hunter

> ORDERED that the portion of this action involving the question of which portions of the information, research and test data submitted by plaintiff in support of applications for registration or tolerances contain or relate to trade secrets or commercial or financial information which is privileged or confidential be, and it is hereby, remanded to the Administrator of the Environmental Protection Agency for his determination under the proper legal standard set forth herein.

At the time of the order, no data could be relied on pursuant to §3(c)(1)(D) if they were protected from disclosure by §10(b), the trade secrets provision. The 1978 amendments removed this qualification from §3(c)(1)(D), however. Consequently, EPA need not make this determination anymore. We thus grant EPA's motion to delete this paragraph from the order.

In Paragraph No. 4, Judge Hunter

> ORDERED and declared that §3(c)(1)(D) of FIFRA, as amended, precludes defendant, without prior permission of plaintiff, from considering in support of another's application for registration any information, research and test data submitted by plaintiff to the Administering Agencies on or after January 1, 1970, which does not contain or relate to trade secrets or commercial or financial information which is privileged or confidential unless such other applicant shall first have made a valid and binding offer to plaintiff to pay reasonable compensation to plaintiff for producing such data.

In Paragraph No. 10, he

> ORDERED that defendant, his officers, agents, employees and representatives be, and they are hereby, forever and permanently enjoined from considering or using any information, research and test data submitted by plaintiff to the Administering Agencies on or after January 1, 1970, which does not contain or relate to trade secrets or other confidential or privileged commercial or financial information in support of any application for registration in which an applicant seeks to rely on such data until such time as the Administrator shall have obtained the express written permission of plaintiff or the subsequent applicant shall first have made to plaintiff a valid and binding offer to pay reasonable compensation to plaintiff for use of the data.

Both of these paragraphs affect EPA's use of nontrade secret data. They are inconsistent with §3(c)(1)(D), which, as we have said, permits EPA to use data submitted on or after January 1, 1970, to support other applications without the permission of the data submitter (unless the data submitter is eligible for the exclusive use provision). The data submitter may receive compensation for use of his data for a period of 15 years after he has submitted them, but when that period expires, the data become noncompensable.

We therefore modify Paragraphs Nos. 4 and 10 so that they reflect this construction of §3(c)(1)(D).

EPA also had sought the deletion of Paragraph No. 2, by which Judge Hunter

> ORDERED and declared that the term "trade secret" as utilized in §10 of FIFRA, as amended, means ". . . any formula, pattern, device or compilation of

information which is used in one's business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it," Restatement, Torts, Section 757, Comment b (1939), taking into account these factors set forth in the Restatement of Torts and in Senate Report 92-838 (Part ii), 92d Cong., 2d Sess., p.72.

In its Supplemental Memorandum, EPA withdrew its request that this paragraph be deleted.

An order follows.

/s/ Barron P. McCune
Barron P. McCune
United States District Judge

Dated: June 12, 1981.

cc: Counsel of record.

IN THE
UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT
OF PENNSYLVANIA

Civil Action No. 81-373

MOBAY CHEMICAL CORPORATION,
Plaintiff,

vs.

DOUGLAS M. COSTLE, Administrator, U.S.
Environmental Protection Agency,
Defendant.

ORDER

AND NOW, June 12, 1981, the motion of defendant is granted in the following respects:

Paragraph No. 9 of the Order entered by Judge Hunter of March 14, 1978, is deleted.

Paragraph No. 3 is deleted.

Paragraphs Nos. 4 and 10 are modified so as to conform to this memorandum.

Each party is to bear his own costs.

/s/ Barron P. McCune
Barron P. McCune
United States District Judge

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APPENDIX C

(Filed July 23, 1981)

IN THE
UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT
OF PENNSYLVANIA

CIVIL ACTION NO. 80-2400

PENNWALT CORPORATION
Pennwalt Building
Three Parkway
Philadelphia, Pennsylvania 19102

v.

UNITED STATES ENVIRONMENTAL
PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

and

DOUGLAS M. COSTLE
Administrator, United States
Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

MEMORANDUM OF DECISION

McGLYNN, J. July 23rd, 1981

Plaintiff Pennwalt Corporation, a producer of agricultural pesticides, challenges the constitutionality of the 1978 amendments to the Federal Insecticide, Fungicide,

and Rodenticide Act (THE ACT), 7 U.S.C.A. §§ 136-136(y) (1980) as well as certain regulations promulgated by the Environmental Protection Agency (EPA). It seeks declaratory and injunctive relief from the operation of the challenged portions of the Act and the EPA's regulatory practice and procedure as set forth in the regulations.

In essence, Pennwalt attacks two features of the Act's new regulatory scheme. First, Pennwalt challenges EPA's use of data submitted by one applicant to support the application for registration filed by another applicant under section 3 of FIFRA. Second, Pennwalt challenges the disclosure provisions of section 10 of the Act, which make certain trade secret data submitted to EPA available to the public. Pennwalt filed a motion for a preliminary injunction seeking to enjoin EPA from enforcing the section 3 use provisions and the section 10 disclosure provisions. On April 10, 1981, the Court issued an order denying the preliminary injunction as to the section 3 claims, and granting the preliminary injunction as to the section 10 claims.

Presently before the Court are cross-motions for summary judgment.

Since 1947, the Act has regulated the manufacture and sale of pesticides and, in so doing, has required Pennwalt to submit test data to the federal government demonstrating the product's efficacy and safety. Prior to 1972, the Act did not prohibit the regulating agency from using submitted data to support the registration of other applicants. Similarly, although the 1947 provisions of the Act specifically prohibited revelation of product formulas, they contained no prohibition against disclosure of other information. It was the regulating agency's practice, however, to use data submitted by a prior applicant when

considering the registrations of other applicants, but not to disclose such information.[1]

In 1972, by amending the Act with the Federal Environmental Pesticide Control Act of 1972, Pub. L. No. 92-516, 86 Stat. 973, Congress reconstructed the entire regulatory scheme, legislating for the first time on the use and disclosure of submitted data. Section 10 of that Act, 7 U.S.C. § 136h (1970 Supp. II), allowed applicants to designate which portions of data were trade secrets and prohibited EPA from publicly disclosing such information. The statute further provided that trade secret data that was prohibited from public disclosure by section 10 could not be used in support of another's registration application.[2]

The 1972 amendments were ambiguous in several respects, including their effective date.[3] Congress remedied

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1. *See* the study by the EPA Office of Pesticide Programs, *FIFRA: Impact on the Industry*, reprinted in S. Rep. 95-334, 95th Cong., 1st Sess. 34 (1977).

2. For registration purposes, data submitted by pesticide applicants was separated into two categories: that data which was trade secret information within the meaning of section 10(b), and that which was not. The 1972 amendments did not define trade secrets. A trade secret under section 10(a) was anything an applicant wanted to so designate, unless EPA could obtain a judgment overturning the designations. EPA was prohibited by section 3(c)(1)(D) from considering trade secret data in support of other registration applications without the permission of the original data submitter. EPA could use all other information in support of other applications, but it had to make the new applicant pay "reasonable compensation" to the earlier applicant.

3. *See Chevron Chemical Co. v. Costle*, 641 F.2d 104, 109 (3d Cir. 1981) *cert. denied* 49 U.S.L.W. 3950 (1981), wherein the Court stated:

> [t]he 1972 Act left major retroactivity questions unanswered: (1) whether firms which had submitted data prior to the effective date of the 1972 Act could retroactively designate that data as trade secrets; (2) whether they were entitled to compensation for such previously submitted data; and (3) whether section 3(c)(1)(D) applied to new applications filed before its effective date. (footnotes omitted).

the confusion with the 1975 amendments to the Act, which provided that the 1972 use and disclosure provisions applied only to data submitted on or after January 1, 1970. Pub.L.No. 94-140, 89 Stat. 751.

In 1978 Congress again amended the Act substantially altering both the use and disclosure provisions. Federal Pesticide Act of 1978, Pub.L.No. 95-396, 92 Stat. 819. Section 3(c)(1)(D) was rewritten to remove the prohibition against EPA using data classified as trade secret when considering another's registration application. That section now provides a comprehensive scheme governing EPA's use of submitted data. It is divided into three categories: 1) data submitted in support of a pesticide registered after September 30, 1978 is entitled to exclusive use for ten years from the date of registration, during which time it cannot be considered in support of another application without the original data submitter's permission; 2) data submitted after December 31, 1969 is provided a period of fifteen years of use with compensation, either by negotiation or by mandatory, nonreviewable arbitration; and 3) data whose period of exclusivity or use with compensation has expired is available for unlimited use.

Broader disclosure provisions were provided with the addition of section 10(d), allowing EPA to disclose safety and efficacy data irrespective of its classification as trade secret. with certain limited exceptions.[4] Under section 10(c), however, EPA must give the submitter thirty days notice before disclosing information claimed to be trade secret. Moreover, under section 10(g), EPA cannot disclose trade secrets to businesses engaged in the production, sale, or distribution of pesticides outside the United States

4. There are three types of information that EPA is not authorized to disclose: manufacturing processes, inert ingredients, and methods for testing such ingredients.

or to anyone who intends to give data to a foreign or multinational business.

Pennwalt's challenges to the 1978 amendments go to both the use and disclosure provisions of the statute. With regard to the provisions allowing the consideration of submitted data to support subsequent applications, Pennwalt claims that: 1) the statute does not authorize EPA's use of pre-January 1, 1970 data and the use of such data is an uncompensated taking in violation of the fifth amendment; 2) the use of post-1970 data is a taking for private rather than public purpose in violation of due process; 3) the binding arbitration scheme unconstitutionally precludes a judicial determination of just compensation; and 4) if a Tucker Act remedy is available, it is inadequate under the circumstances.

In a recent case in which the plaintiff attacked the identical use provisions on essentially the same grounds, the Third Circuit held that the plaintiff did not have a property right of non-use by the government in data voluntarily submitted to the government. *Chevron Chemical Co. v. Costle*, 641 F.2d 104 (3d Cir. 1981), *cert. denied*, 49 U.S.L.W. 3950 (1981). Because the Court found no property right which would prevent internal agency use of the data, there was no need to reach the constitutional issues relating to the taking of plaintiff's property.

The Court reasoned that, before federal due process protections apply, there must be an entitlement created by law. *Id.* at 114, *citing Paul v. Davis*, 424 U.S. 693 (1976). Looking first to federal law, the Court stated that federal protection of intellectual property is statutory and that prior to 1971, when section 3(c)(1)(D) of the ACT conferred a property right in some data submitted to EPA, the only federal statute pertinent was 18 U.S.C. § 1905. Because section 1905 provides criminal penalties for the

unauthorized disclosure of trade secret data by federal officers or employees, the Court found that at best section 1905 could outline a federal law right of non-disclosure, not of non-use by the agency.

Because it found no federal law property interest, the Court looked to state law to see if it conferred a property interest in the data. Plaintiff argued that section 757 of the Restatement of Torts (1939) created such an interest. But the Court noted that section 757 deals with liability for disclosure of trade secrets without a privilege to do so,[5] and it therefore could create a property interest of agency non-disclosure only. Moreover, the Court voiced a concern that Supremacy Clause considerations might override a state law defining the confidentiality with which federal agencies are to treat submitted data.

In summary, the Court found that, prior to 1972, 18 U.S.C. § 1905 and agency practice defined the scope of plaintiff's expectation of privacy in data submitted to EPA, and since 1972 the various versions of section 3(c)(1)(D) had done so.[6] The Court therefore concluded that plaintiff had no property right of agency non-use other than those provided in section 3(c)(1)(D).

Chevron thus authorized EPA's use of pre-1970 data without the original data submitter's consent and EPA's

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5. Section 757 provides in pertinent part:

One who discloses or uses another's trade secret, without a privilege to do so, is liable to the other if

(a) he discovered the secret by improper means, or

(b) his disclosure or use constitutes a breach of confidence reposed in him by the other in disclosing the secret to him. . . .

6. The Court in *Chevron* found that prior to 1972 it had been agency practice to use data submitted by an earlier applicant when considering a later applicant's request for registration. *Id.* at 109.

use of post-1969 data in conformity with the provisions of 3(c)(1)(D). Because I find that Pennwalt's challenges to section 3 are essentially the same as those advanced by plaintiff in *Chevron*, I will grant summary judgment in favor of EPA on Pennwalt's section 3 claims.

The second prong of Pennwalt's attack on the Act is against the section 10 disclosure provisions. Pennwalt contends that: 1) the disclosure of trade secret data constitutes a taking for a private rather than a public purpose, and, even if it were for a public purpose, the taking is retroactive without just compensation, all in violation of due process; 2) the notice requirements of section 10(d) are insufficient, thereby violating due process; 3) section 10(g), which prohibits EPA from knowingly disclosing submitted information to a foreign or a multinational pesticide producer, is deficient because EPA has not enacted any regulations to enforce that provision; 4) the disclosure of trade secret data violates the Trade Secrets Act, 18 U.S.C. §1905, and therefore may be enjoined under section 10(e) of the Administrative Procedure Act (APA), 5 U.S.C. § 706(2)(A); and 5) any Tucker Act remedy available is inadequate and unreasonable because Pennwalt's data is of virtually incalculable value.[7]

For the purposes of Pennwalt's section 10 claims, I assume *arguendo* that there is a valid property interest at stake and proceed to the merits of Pennwalt's claims. Pennwalt argues that disclosure of its trade secret data constitutes a taking of its property because it will destroy

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7. Pennwalt does not argue that the 1978 amendments to section 10 of FIFRA apply prospectively only. Other courts have impliedly held that these provisions apply retroactively to pre-1970 data. *See Mobay Chemical Corp. v. Costle*, C.A. No. 81-373, slip op. at 25-29 (W.D.Pa. filed June 16, 1981); *Petrolite Corporation v. United States Environmental Protection Agency*, C.A. No. 80-0798, slip op. at 10-11 (D.D.C. filed June 25, 1981). We see no reason to disagree with those holdings.

the secrecy aspect of the data. It is a generally recognized principle, however, that Congress may encroach upon property rights if such action bears a reasonable relationship to a permissible police power. *United States v. Darby*, 312 U.S. 100 (1941).

The Supreme Court has consistently upheld the right of the government to require manufacturers to disclose to the public information concerning the nature of the products which they are selling. In *Corn Products Refining Co. v. Eddy*, 249 U.S. 427 (1919), a manufacturer claimed that a state statute requiring public disclosure of its product's confidential formula constituted a taking. The Court held that a manufacturer has no constitutional right to sell goods without giving the public fair information about the product. The Court broadened this holding in *National Fertilizer v. Bradley*, 301 U.S. 178 (1937), by sustaining retroactive regulation of products manufactured before the regulating statute was enacted.

While recognizing that it has been unable to develop a "set formula" for determining when governmental action constitutes a taking, the Supreme Court recently identified several critical factors to be considered within the factual context of each case: 1) the nature of the government's encroachment on the property, 2) its impact on the owner's use of the property, and 3) the character of the governmental action in relation to its legislative purposes. *See Penn Central Transportation Co. v. New York City*, 438 U.S. 104, 124 (1978).

Section 10(d) of the Act makes all hazard and efficacy data available to the public, the obvious purpose being to allow the public access so that they may judge for themselves how toxic the pesticides are to which they are exposed. Section 10(d) therefore serves the legitimate function of informing the public of pesticide dangers.

Furthermore, disclosure of data voluntarily submitted in order to gain a license is not an overly intrusive means of achieving that end.

Although Pennwalt produced its data at great expense after years of research, the natural assumption is that it did so to develop and register its product without regard to potential disclosure. *See Petrolite Corporation v. United States Environmental Protection Agency*, C.A. No. 80-0798 slip. op. at 8 (D.D.C. filed June 25, 1981). Pennwalt has exchanged its right to prevent disclosure of the data in return for the right to sell its goods in interstate commerce. The data still serves its most important function, *i.e.*, it helps Pennwalt to develop the pesticides and to have them registered for use in interstate commerce.

I do not minimize the loss of competitive advantage that disclosure will cause Pennwalt to suffer, but some degree of interference must result when a public program adjusts the benefits and burdens of economic life to promote the common good. *Penn Central Transportation Co. v. New York City*, 438 U.S. 104, 124 (1978). In this instance the interference is not so great as to constitute a taking within the meaning of the Fifth Amendment. Rather, it is the cost of "doing business in a civilized community." *Pennsylvania Coal Co. v. Mahon*, 160 U.S. 393, 422 (1922) (Brandeis dissenting).

The remainder of Pennwalt's challenges to section 10 may be dealt with more briefly. Pennwalt argues that the disclosure provisions retroactively destroy vested property rights thereby violating due process. For this claim to be sustained, Pennwalt must bear the burden of showing that the statute operates irrationally. *Williamson v. Lee Optical Co.*, 348 U.S. 483 (1955). The legislative history of the statute shows that Congress carefully legislated to provide a system whereby potential hazards were dis-

closed to the public. Pennwalt has made no argument to support a claim that the provisions are an irrational means of implementing that Congressional goal. Consequently this claim must fail.

Pennwalt contends that disclosure of data under section 10 violates due process because section 10 provides for notice to the data submitter only when the data falls within sections 10(d)(1)(A), (B), or (C) or section 10 (d)(2). Because I have decided that the disclosure provisions do not effect a taking of property without just compensation, Pennwalt's claim that EPA must give it notice and a hearing before it discloses such data must also fail.

Pennwalt also asserts that EPA has promulgated no regulations or procedures to ensure that section 10(g), which prohibits the release of submitted information to foreign or multinational pesticide producers, will be adequately enforced. EPA has promulgated interim procedures to protect submitted test data from being disclosed to foreign or multinational corporations. 43 Fed. Reg. 59070, 59062 (December 19, 1978). These interim procedures require any person who intends to inspect the data to submit an affirmation that he is not seeking access to the data in order to provide it to a foreign or multinational pesticide producer. EPA has also developed, and has in use, a form for affirmation for this purpose. I find these procedures adequate to protect Pennwalt's data from the potential harm, even though they are not yet promulgated in final form.

Pennwalt contends that the disclosure provisions violate the Trade Secrets Act, 18 U.S.C. § 1905, and must therefore be set aside as "not in accordance with law" within the meaning of section 10(e) of the Administrative Procedures Act (APA), 5 U.S.C. § 706(2)(A). The Trade

Secrets Act does not confer a private cause of action. *Chrysler Corp. v. Brown*, 441 U.S. 281 (1979). Section 10(a) of the APA, however, provides that "[a] person suffering legal wrong because of agency action, or aggrieved by agency action . . . is entitled to judicial review thereof." 5 U.S.C. § 702. Although Pennwalt cannot avail itself of a private cause of action under section 1905, any violation thereof may be dispositive of the outcome of judicial review under section 10(e) of the APA.

Pennwalt advances no arguments suggesting how disclosure will violate section 1905. But for a claim to be successful under section 1905, the suspect disclosure must be "not authorized by law."[8] Since section 10 of the Act authorizes the disclosures EPA contemplates, any claims under section 1905 must be grounded in the unconstitutional taking and due process arguments that Pennwalt contends invalidate section 10. Because I have discussed those arguments earlier in this opinion and found that Pennwalt cannot prevail on them, it is not necessary to deal with them separately here. Accordingly, Pennwalt's claim under section 1905 and section 10(e) of the APA also fails.

Pennwalt's last argument is that, because Pennwalt's data is of incalculable value, damage arising from disclosure of that data cannot be adequately remedied by pursuing a claim in the Court of Claims under the Tucker

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8. The Trade Secrets Act provides in pertinent part:

> Whoever, being an officer or employee of the United States or of any department or agency thereof, publishes, divulges, discloses, or makes known in any manner or to any extent not authorized by law any information coming to him in the course of his employment or official duties . . . which information concerns or relates to the trade secrets, processes, operations, style of work, . . . shall be fined not more than $1,000, or imprisoned not more than one year, or both; and shall be removed from office or employment. (emphasis added).

Act. Because I have decided that the disclosure provisions do not constitute a taking, Pennwalt is not entitled to relief under the Tucker Act. The adequacy and reasonableness of relief obtained pursuant to the Tucker Act therefore is not at issue.

For the foregoing reasons, defendants' motion for summary judgment will be granted and plaintiff's motion for summary judgment will be denied.

IN THE
UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT
OF PENNSYLVANIA

CIVIL ACTION NO. 80-2400

PENNWALT CORPORATION
Pennwalt Building
Three Parkway
Philadelphia, Pennsylvania 19102

v.

UNITED STATES ENVIRONMENTAL
PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

and

DOUGLAS M. COSTLE
Administrator, United States
Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

ORDER

AND NOW, this 23rd day of July, 1981, upon consideration of cross-motions for summary judgment it is

ORDERED

that plaintiff's motion be and the same is hereby DENIED and that defendants' motion be and the same is hereby GRANTED. It is further ORDERED that the preliminary injunction enjoining defendants is dissolved.

By the Court

/s/ Joseph L. McGlynn, Jr.
Joseph L. McGlynn, Jr. J.

(Filed July 23, 1981)

IN THE
UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT
OF PENNSYLVANIA

CIVIL ACTION NO. 80-2400

PENNWALT CORPORATION
Pennwalt Building
Three Parkway
Philadelphia, Pennsylvania 19102

v.

UNITED STATES ENVIRONMENTAL
PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

and

DOUGLAS M. COSTLE
Administrator, United States
Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

JUDGMENT ORDER

AND NOW, this 23rd day of July, 1981, in accordance with the Memorandum of Decision and accompanying Order of this date, it is hereby

ORDERED

that Judgment be and the same is hereby entered in favor of the defendants, United States Environmental Protection Agency and Douglas M. Costle, Administrator of the United States Environmental Protection Agency, and against the plaintiff, Pennwalt Corporation.

By the Court

/s/ Joseph L. McGlynn, Jr.
Joseph L. McGlynn, Jr. J.

APPENDIX D

Section 3(c)(1)(D) of FIFRA, as amended in 1978, provides:

"(c) *Procedure for Registration.*—

(1) *Statement required.*—Each applicant for registration of a pesticide shall file with the Administrator a statement which includes—

* * *

(D) except as otherwise provided in subsection (c)(2)(D) of this section, if requested by the Administrator, a full description of the tests made and the results thereof upon which the claims are based, or alternatively a citation to data that appears in the public literature or that previously had been submitted to the Administrator and that the Administrator may consider in accordance with the following provisions:

(i) with respect to pesticides containing active ingredients that are initially registered under this Act after September 30, 1978, data submitted to support the application for the original registration of the pesticide, or an application for an amendment adding any new use to the registration and that pertains solely to such new use, shall not, without the written permission of the original data submitter, be considered by the Administrator to support an application by another person during a period of ten years following the date the Administrator first registers the pesticides: Provided, That such permission shall not be required in the case of defensive data;

(ii) except as otherwise provided in subparagraph (D)(i) of this paragraph, with respect

to data submitted after December 31, 1969, by an applicant or registrant to support an application for registration, experimental use permit, or amendment adding a new use to an existing registration, to support or maintain in effect an existing registration, or for reregistration, the Administrator may, without the permission of the original data submitter, consider any such item of data in support of an application by any other person (hereinafter in this subparagraph referred to as the 'applicant') within the fifteen-year period following the date the data were originally submitted only if the applicant has made an offer to compensate the original data submitter and submitted such offer to the Administrator accompanied by evidence of delivery to the original data submitter of the offer. The terms and amount of compensation may be fixed by agreement between the original data submitter and the applicant, or, failing such agreement, binding arbitration under this subparagraph. If, at the end of ninety days after the date of delivery to the original data submitter of the offer to compensate, the original data submitter and the applicant have neither agreed on the amount and terms of compensation nor on a procedure for reaching an agreement on the amount and terms of compensation, either person may initiate binding arbitration proceedings by requesting the Federal Mediation and Conciliation Service to appoint an arbitrator from the roster of arbitrators maintained by such Service. The procedure and rules of the Service shall be applicable to the selection of such arbitrator and to such arbitration proceedings, and the findings and determination of

the arbitrator shall be final and conclusive, and no official or court of the United States shall have power or jurisdiction to review any such findings and determination, except for fraud, misrepresentation, or other misconduct by one of the parties to the arbitration or the arbitrator where there is a verified complaint with supporting affidavits attesting to specific instances of such fraud, misrepresentation, or other misconduct. The parties to the arbitration shall share equally in the payment of the fee and expenses of the arbitrator. If the Administrator determines that an original data submitter has failed to participate in a procedure for reaching an agreement or in an arbitration proceeding as required by this subparagraph, or failed to comply with the terms of an agreement or arbitration decision concerning compensation under this subparagraph, the original data submitter shall forfeit the right to compensation for the use of the data in support of the application. Notwithstanding any other provision of this Act, if the Administrator determines that an applicant has failed to participate in a procedure for reaching an agreement or in an arbitration proceeding as required by this subparagraph, or failed to comply with the terms of an agreement or arbitration decision concerning compensation under this subparagraph, the Administrator shall deny the application or cancel the registration of the pesticide in support of which the data were used without further hearing. Before the Administrator takes action under either of the preceding two sentences, the Administrator shall furnish to the affected person, by certified mail, notice of intent to take actions and allow

fifteen days from the date of delivery of the notice for the affected person to respond. If a registration is denied or canceled under this subparagraph, the Administrator may make such order as the Administrator deems appropriate concerning the continued sale and use of existing stocks of such pesticide. Registration action by the Administrator shall not be delayed pending the fixing of compensation;

(iii) after expiration of any period of exclusive use and any period for which compensation is required for the use of an item of data under subparagraphs (D)(i) and (D)(ii) of this paragraph, the Administrator may consider such item of data in support of an application by any other applicant without the permission of the original data submitter and without an offer having been received to compensate the original data submitter for the use of such item of data;"

Section 3(c)(2)(A) of FIFRA, as amended in 1978, provides:

"*Data in support of registration.*—The Administrator shall publish guidelines specifying the kinds of information which will be required to support the registration of a pesticide and shall revise such guidelines from time to time. If thereafter he requires any additional kind of information under subparagraph (B) of this paragraph, he shall permit sufficient time for applicants to obtain such additional information. The Administrator, in establishing standards for data requirements for the registration of pesticides with respect to minor uses, shall make such standards commensurate with the anticipated extent of use, pattern of use, and the level and degree of potential

exposure of man and the environment to the pesticide. In the development of these standards, the Administrator shall consider the economic factors of potential national volume of use, extent of distribution, and the impact of the cost of meeting the requirements on the incentives for any potential registrant to undertake the development of the required data. Except as provided by section 10, within 30 days after the Administrator registers a pesticide under this Act he shall make available to the public the data called for in the registration statement together with such other scientific information as he deems relevant to his decision."

Section 10 of FIFRA, as amended in 1978, provides:

"SEC. 10. PROTECTION OF TRADE SECRETS AND OTHER INFORMATION.

(a) *In General.*—In submitting data required by this Act, the applicant may (1) clearly mark any portions thereof which in his opinion are trade secrets or commercial or financial information and (2) submit such marked material separately from other material required to be submitted under this Act.

(b) *Disclosure.*—Notwithstanding any other provision of this Act, and subject to the limitations in subsections (d) and (e) of this section the Administrator shall not make public information which in his judgment contains or relates to trade secrets or commercial or financial information obtained from a person and privileged or confidential, except that, when necessary to carry out the provisions of this Act, information relating to formulas of products acquired by authorization of this Act may be revealed to any Federal agency consulted and may be revealed at a public hearing or in findings of fact issued by the Administrator.

(c) *Disputes.*—If the Administrator proposes to release for inspection information which the applicant or registrant believes to be protected from disclosure under subsection (b), he shall notify the applicant or registrant, in writing, by certified mail. The Administrator shall not thereafter make available for inspection such data until thirty days after receipt of the notice by the applicant or registrant. During this period, the applicant or registrant may institute an action in an appropriate district court for a declaratory judgment as to whether such information is subject to protection under subsection (b).

(d) *Limitations.*—

(1) All information concerning the objectives, methodology, results, or significance of any test or experiment performed on or with a registered or previously registered pesticide or its separate ingredients, impurities, or degradation products, and any information concerning the effects of such pesticide on any organism or the behavior of such pesticide in the environment, including, but not limited to, data on safety to fish and wildlife, humans and other mammals, plants, animals, and soil, and studies on persistence, translocation and fate in the environment, and metabolism, shall be available for disclosure to the public: *Provided*, That the use of such data for any registration purpose shall be governed by section 3 of this Act: *Provided further*, That this paragraph does not authorize the disclosure of any information that—

(A) discloses manufacturing or quality control processes,

(B) discloses the details of any methods for testing, detecting, or measuring the quantity of any deliberately added inert ingredient of a pesticide, or

(C) discloses the identity or percentage quantity of any deliberately added inert ingredient of a pesticide, unless the Administrator has first determined that disclosure is necessary to protect against an unreasonable risk of injury to health or the environment.

(2) Information concerning production, distribution, sale, or inventories of a pesticide that is otherwise entitled to confidential treatment under subsection (b) of this section may be publicly disclosed in connection with a public proceeding to determine whether a pesticide, or any ingredient of a pesticide, causes unreasonable adverse effects on health or the environment, if the Administrator determines that such disclosure is necessary in the public interest.

(3) If the Administrator proposes to disclose information described in clause (A), (B), or (C) of paragraph (1) or in paragraph (2) of this subsection, the Administrator shall notify by certified mail the submitter of such information of the intent to release such information. The Administrator may not release such information, without the submitter's consent, until thirty days after the submitter has been furnished such notice: *Provided*, That where the Administrator finds that disclosure of information described in clause (A), (B), (C) of paragraph (1) of this subsection is necessary to avoid or lessen an imminent and substantial risk of injury to the public health, the Administrator may set such shorter period of notice (but not less than ten days) and such method of notice as the Administrator finds appropriate. During such period the data submitter may institute an action in an appropriate district court to enjoin or limit the proposed disclosure. The court shall give expedited considera-

tion to any such action. The court may enjoin disclosure, or limit the disclosure or the parties to whom disclosure shall be made, to the extent that—

(A) in the case of information described in clause (A), (B), or (C) of paragraph (1) of this subsection, the proposed disclosure is not required to protect against an unreasonable risk of injury to health or the environment; or

(B) in the case of information described in paragraph (2) of this subsection, the public interest in availability of the information in the public proceeding does not outweigh the interests in preserving the confidentiality of the information.

(e) *Disclosure to Contractors.*—Information otherwise protected from disclosure to the public subsection (b) of this section may be disclosed to contractors with the United States and employees of such contractors if, in the opinion of the Administrator, such disclosure is necessary for the satisfactory performance by the contractor of a contract with the United States for the performance of work in connection with this Act and under such conditions as the Administrator may specify. The Administrator shall require as a condition to the disclosure of information under this subsection that the person receiving it take such security precautions respecting the information as the Administrator shall by regulation prescribe.

(f) *Penalty for disclosure by Federal Employees.*—

(1) Any officer or employee of the United States or former officer or employee of the United States who, by virtue of such employment or official position,

has obtained possession of, or has access to, material the disclosure of which is prohibited by subsection (b) of this section, and who, knowing that disclosure of such material is prohibited by such subsection, willfully discloses the material in any manner to any person not entitled to receive it, shall be fined not more than $10,000 or imprisoned for not more than one year, or both. Section 1905 of title 18 of the United States Code shall not apply with respect to the publishing, divulging, disclosure, or making known of, or making available, information reported or otherwise obtained under this Act. Nothing in this Act shall preempt any civil remedy under State or Federal law for wrongful disclosure of trade secrets.

(2) For the purposes of this section, any contractor with the United States who is furnished information as authorized by subsection (e) of this section, or any employee of any such contractor, shall be considered to be an employee of the United States.

(g) *Disclosure to Foreign and Multinational Pesticide Producers.*—

(1) The Administrator shall not knowingly disclose information submitted by an applicant or registrant under this Act to any employee or agent of any business or other entity engaged in the production, sale, or distribution of pesticides in countries other than the United States or in addition to the United States or to any other person who intends to deliver such data to such foreign or multinational business or entity unless the applicant or registrant has consented to such disclosure. The Administrator shall require an affirmation from any person who intends to inspect data that such person does not seek access

to the data for purposes of delivering it or offering it for sale to any such business or entity or its agents or employees and will not purposefully deliver or negligently cause the data to be delivered to such business or entity or its agents or employees. Notwithstanding any other provision of this subsection, the Administrator may disclose information to any person in connection with a public proceeding under law or regulation, subject to restrictions on the availability of information contained elsewhere in this Act, which information is relevant to the determination by the Administrator with respect to whether a pesticide, or any ingredient of a pesticide, causes unreasonable adverse effects on health or the environment.

(2) The Administrator shall maintain records of the names of persons to whom data are disclosed under this subsection and the persons or organizations they represent and shall inform the applicant or registrant of the names and affiliation of such persons.

(3) Section 1001 of title 18 of the United States Code shall apply to any affirmation made under paragraph (1) of this subsection.